VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH AND DEVELOPMENT SERVICE PROGRAMS

Margaret J. Giannini, M.D., Director

Development and Evaluation of a New Artificial Larynx

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The purpose of this project is to develop a neck vibration device that is cosmetically pleasing, has effective contact over a wide range of anatomical structures, can be fitted to the neck for extended periods, has a choice of activation modalities, and will facilitate production of highly intelligible speech in a wide range of acoustic environments.

A mathematical model was developed for predicting dynamics of the electromechanical oscillator. An optimization study, involving computer simulation and subject testing, was completed, leading to improved acoustic performance of the system. Mechanical adjustments of the electromechanical oscillator of the artificial larynx were finalized.

In an effort to finalize the complete system, extensive field testing will be accomplished for integration of oscillator, power supply, activation and neck mounting (plus cosmetics).

Studies of Normal and Abnormal Motion

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The project has two major objectives: (i) to document ranges of normal variability for the walking performance, standing balance, strength, and other aspects of human functional performance; (ii) to use these normal standards as a basis of comparison for evaluating the effectiveness of treatment procedures in improving the functional performance of patients with selected chronic neuro-musculoskeletal disabilities.

In previous work, the Kinesiology Research Laboratory documented the simultaneous displacement patterns of 20 body parts during the free-speed and fast walking of normal men and women in wide ranges of age and height. This normal data was then used as a basis for characterizing the gait abnormalities of patients with unilateral hip fusion, unilateral hip pain, unilateral above-knee amputation, unilateral excision of the triceps surae, and parkinsonism. In order to better understand the causation of gait abnormalities, methods were developed to measure forces applied to canes and crutches, strength of muscles about the hip and knee, weight-supporting ability, and postural steadiness and stability. Standards of normal variability for many of these components of function were established for normal subjects in various age groups. A multi-faceted approach was then taken toward studying the functional performance of patients before and after total joint replacements for arthritis of the hip or knee. In a series of studies, the preoperative to postoperative changes in function (gait, use of assistive devices, muscle strength, range of joint motion, and weight-bearing ability) were assessed at intervals after surgery. Questions were answered such as: When is improvement in function after hip or knee replacement most likely to occur? Will improvement continue up to four years after surgery? In which specific components of function do the largest deficits from normal remain after surgery? Does the type of prosthesis used make a difference in function?

During the period between July 1, 1981 and December 31, 1981, a study was published which was designed to answer whether osteotomy of the greater trochanter improves function in patients with total hip replacement. The study compared two similar groups of 40 patients with Muller total hip replacements, one with and one without osteotomy of the greater trochanter (1). Except for the total hip replacement, each of the patients was without disability. Subjective ratings of pain and of the status of the hip after surgery were slightly more favorable in the group with osteotomy. In each group, 57% reduced their need for assistive devices by 2 years after surgery. Those with osteotomy who used canes after surgery applied higher cane forces than those without osteotomy. The group with osteotomy improved slightly more in some hip motions than the other group. In measures of hip muscle strength, weight-bearing ability and gait, no statistical significant differences were found between the groups. The findings suggested that osteotomy provides no functional advantages to the patient beyond those of total hip replacement without osteotomy.

Another in the series of total joint replacements will be published assessing whether differences in function can be measured between groups of patients with the same type of hip replacement but with different incision sites; in one group the anterolateral muscles are cut through and, in the other, the posterior muscles of the hip are cut through in order to insert the hip replacement. Preoperative and postoperative data will continue to be collected for longitudinal studies of the effectiveness of different types of hip and knee arthroplasties in improving the functional performance of patients with hip and knee arthritis.

Publications

1. Murray MP, Gore DR, Brewer BJ, Gardner GM, Sepic SB: Comparison of Muller total hip replacement with and without trochanteric osteotomy: Kinesiologic measurements of 82 cases 2 years after surgery. Acta Orthop Scand 52: 345–352, 1981.

Development of a Wheelchair Using a Myoelectric Control System

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The purpose of this program is to investigate the potential use of consciously controlled myoelectric activity for the operation of motorized wheelchairs. Efforts previous to the period covered by this progress report have resulted in the successful development of an experimental myoelectric control system that replaces the popular type of joystick which employs a set of microswitches for constant speed control. The positive results of this project paved the way for developing a proportionally-controlled myoelectric wheelchair drive system. Plans for the unit were presented in the BPR 10-36 progress report.

A myoelectric proportionally-controlled system has been developed during the July through December 1981 reporting period. An experimental unit has been constructed (with the exception of the hardware required for operation in the reverse direction) and used by the experimentors to successfully operate a wheelchair. The proportionally-controlled version of the myoelectric wheelchair drive has not yet been tested with patients.

Although the program is currently slowed due to an interruption of funding, plans are being made to: (i) add the direction-reversing hardware, (ii) train high-level quadriplegic patients to operate the experimental unit, and (iii) to design and construct a prototype unit that is smaller than the currently operative experimental system.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prostheses and Orthoses

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Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

The purpose of this project is to determine practicality and usefulness of the JHU/APL robotic arm/worktable system and associated assistive devices for high spinal cord injured persons. Engineering development to improve system operation continues.

The JHU/APL robotic arm/worktable system has been in engineering development and limited clinical evaluation since 1974. The latest model consists of a computer-aided robotic arm mounted on a worktable with several sets of work objects. The relative locations of the operator, the sets of work objects, and the arm have been empirically chosen to optimize manipulation of these objects by the arm for performance of useful tasks. Task capabilities currently on-line include self-feeding, sorting and filing reading materials, moving these reading materials to and from a reading stand, moving the stand in and out of the operator's work space, inserting and removing paper from a typewriter, moving the typewriter in and out of the operator's work space, moving a telephone to and from the operator's head, and inserting and removing diskettes from the disk drive of a personal computer system.

A low-profile chin-operated wheelchair controller was also developed. It enables both wheelchair control and robotic arm control through a special infrared signal link to the worktable. Electronic systems for both the chin controller and a hand operated (joystick) controller have been developed which provide closed loop velocity control with automatic downhill braking, steady speed over rough terrain and reduced sensitivity to involuntary hand or chin motions.

A chin-operated Morse code computer interface device was also developed. It enables a high-level spinal-cord-injured person to communicate with a personal computer more rapidly than through a conventional keyboard.

During the July–December 1981 period, progress was made in improving the functional potential of the robotic arm/worktable system for high-spinal-cord-injured persons. A new device was developed to enable such persons to feed themselves from a standard dinner plate with a conventional knife and spoon. This arrangement was tested with various foods and was found to be the most satisfactory one yet devised for self-feeding with this worktable.

In order to reduce robotic arm task performance time without reducing safety or increasing control requirements, the motor-electronic driver design was modified to allow up to 3 axes of combined motion when in the programmed mode. Single axis motion was continued for manual input control. Eighty percent of the conversion of two JHU/APL robotic arm systems to this design has been completed. Following completion of this conversion and appropriate modification of the computer software, these systems will be ready for testing.

One chin-operated wheelchair controller was furnished to a high-level spinal-cord-injured patient at the Fort Howard VA Medical Center for preliminary familiarization prior to testing with the robotic arm/worktable system. This individual had been previously fitted with a sip and puff wheelchair controller while in another institution. After months of testing, it was determined that that individual was unsuccessful in mastering the chin control system, and that test was terminated. Five chin-control systems previously fitted to quadriplegics continued in clinical evaluation testing. All are achieving highly satisfactory results.

An important objective of the FY82 work at JHU/APL was to hold a two-day workshop at each of four VA medical centers, in order to present the concept of the robotic arm/worktable system and to get feedback from VA medical professionals working regularly with spinal-cord-injured persons, and from potential users. One such workshop was held at the VA Medical Center, Richmond, Virginia, in December 1981, and included presentations of system operation and capability using the actual equipment. Approximately 30 per-

sons attended major portions of this seminar. Interest was high and long-term clinical testing at this center was proposed for FY83 using a JHU/APL furnished robotic arm/worktable and wheelchair control system. Three additional workshops are planned at other VA centers during the early part of 1982.

A pseudo-Morse input system

A personal computer has been an option on the JHU/APL robotic arm/worktable for the last year. Inputting the computer by using a mouthstick on the keyboard has been unacceptably slow and tiresome. Furthermore, many programs, such as those of word processors, require multiple key entry. This is difficult or cumbersome with a mouthstick. As an alternative to the keyboard, a new pseudo-Morse code input system was developed. The input device is a commercially available high speed Morse code keyer. It can be operated by limited, small, or poorly coordinated motions of the chin or hand. This device is designed with two small closely aligned paddles which generate a series of dots when pressed in one direction or dashes when pressed in the opposite direction.

One interface card uses a microprocessor Morse converter to the RS-232 port to access standard time-sharing terminals or personal computers such as the APPLE II and Radio Shack TRS-80 Mod I. Another option uses a "transparent" interface card in the APPLE computer to permit running all available software packages. Speeds of 60 characters per minute are easily achievable, and simultaneous key entries such as Shift, Control, Repeat, followed by any key, allow execution of all software commands. In demonstrations in the laboratory with manually handicapped persons operating the computer with the pseudo-Morse code input system, use of word processor programs such as APPLE-WRITER™ or MAGIC WINDOW™, and of financial management programs like VISICALC™ were shown to be practical.

A clinical evaluation program is currently underway in which JHU/APL is furnishing some sample systems to various rehabilitation centers throughout the United States, in order to evaluate the effectiveness of this low-cost interface and its potential for enabling severely handicapped persons greater access to a computer.

A promising by-product of this program is the evolution of a technique for communication by persons with vocal communication problems, e.g., strokes. This technique utilizes the JHU/APL Morse interface board with the APPLE II computer. Its output is complete sentences on a video monitor with access times of five to fifteen seconds for any one of hundreds of messages. Except for the JHU/APL Morse card, it uses all standard low-cost commercially available components and is described elsewhere in this issue of the Bulletin of Prosthetics Research.

Engineering improvement to allow 3 axis motion of the robotic arm will be completed within the next few months. Clinical testing will be continued on the chin controlled wheelchair and robotic arm/worktable system. Three workshops will be held on this system at VA medical centers during the early months of 1982. Evaluation will continue on the JHU/APL Morse/computer interface by this research team, by the Institute of Physical Medicine and Rehabilitation in Peoria, Illinois, by the Trace Research and Development Center for the Severely Communicatively Handicapped in Madison, Wisconsin, by TRIUMF, University of British Columbia in Vancouver, Canada, and by others yet to be designated. Efforts to identify and interest appropriate firms in manufacturing and marketing the chin controller, the closed loop velocity control system, the robotic arm/worktable system and the Morse/computer interface system will be continued.

Advanced Power and Control System for Battery Powered Wheelchairs

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Luther T. Prince, President

The purpose of this project is to develop a wheelchair mounted battery charger and energy monitor system with the desired goal of increasing mobility by providing a more accurate indication of energy remaining in the battery. In addition, the charger will be controlled more precisely, which will utilize battery capacity more optimally and increase battery life.

The energy monitor breadboard has been completed and partially programmed. A high-energy-density nickel zinc battery has been ordered for evaluation. The battery charger design is in process.

Residual Bladder Volume Determination in Spinal Cord Injury Patients

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We have completed our initial simulations of the ultrasound method of measuring bladder volume and decided upon an integration algorithm. Also, a laboratory ultrasonic system has been constructed and used to begin the experimental tests for locating the bladder walls. Those tests have shown the need for applying several correction factors when measuring the bladder wall location. Also, initial simulations of the effect of refraction have shown the importance of this phenomenon.

Future work will consist of extensions of the laboratory tests to more complex geometries and refinements of the refraction simulation to further investigate its importance.

Seat Cushions for the Paralyzed

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Leon Bennett, M.A.E.

Hard seat testing has been completed for pressure, shear, and skin blood flow lateral to the ischial tuberosities of some (16) paraplegic subjects.

To manage the scattered data, the cumulative frequency of occurrence above a given value has been employed. Thus, while no normal subject generated a shear value greater than 30 gm/cm^2, over 35 percent of the para-

plegic results exceeded this value. The median (50 percent data) value of normal blood flow exceeds the corresponding paraplegic value by a factor larger than three fold.

We are preparing a manuscript detailing our results.

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

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The purpose of this project is to devise semiquantitative and quantitative methods to measure pressure on the sole of the foot in health and disease and after surgical procedures, and to devise orthotic devices to treat foot disorders.

We have completed a finite element analysis (See BPR 10-35, pg. 27.) of the foot within the shoe to determine the effects of shoe sole properties. We have calibrated pressure transducers to apply to the sole of the foot.

We are continuing the development of a television monitored, glass plate method for measuring pressures on the sole of the foot. We are now ordering special glass and a color mixer to be able to quantitate pressure. This should be built within the next few weeks. This barograph would be of great value in our efforts to measure pressure.

Seating Systems for Body Support and Prevention of Tissue Trauma

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The Veterans Administration Seating Interface Orthosis (VASIO) is the centerpiece of a total body support system that not only acts as a prophylactic measure against pressure sores, but will also enhance the orthopedic management of the spinal-cord-injured population.

Clinical evaluations of the VASIO-P (the suffix identifies the model for paraplegic use) (Fig. 1) have been completed. Approximately 100 patients participated in the study, of whom 48 continued to be followed for periods ranging from two weeks to one year. Results of the study show the cushion to be effective in redistributing pressures over the seating surface to achieve levels which are well tolerated by the patients. In addition, the subjective comments by the test subjects as regards seating stability, posture, and comfort have been favorable. A commercial version of the cushion is expected to be available in Spring 1982. It will be manufactured by Tumble Forms and marketed through the Preston Corporation.

Research efforts are now being directed toward developing a version of the cushion for quadriplegics (VASIO-Q). The VASIO-Q will address the increased postural needs of the quadriplegic population and provide an additional margin of safety to compensate for their limited or absent ability to perform independent pressure reliefs. Potential cushion designs are currently being evaluated on a limited sample of patients.

Instrumentation for Clinical Investigative Engineering Center

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The laboratory will be used to conduct clinical investigations the immediate technical focus of which is in the area of locomotory impairments. The goal is to enable clinicians to employ objective techniques to (i) help make choices in prosthetic and orthotic treatments, (ii) measure progress and efficacy of therapy, and (iii) evaluate new and untested components, appliances, and treatment techniques.

Construction of instrumentation is nearing completion. Despite a technical delay resulting from the Federal hiring freeze in early 1981, the work is expected to be completed on schedule by March 31, 1982. Instrumentation under construction includes electrogoniometers, load sensing sandals, a tachometer, and a triaxial accelerometer. Data will be sampled, recorded and treated with a Commodore Business Machine "PET" microcomputer.

Construction of a barograph was completed. The barograph employs a white, nubby, silicone elastomer sheet

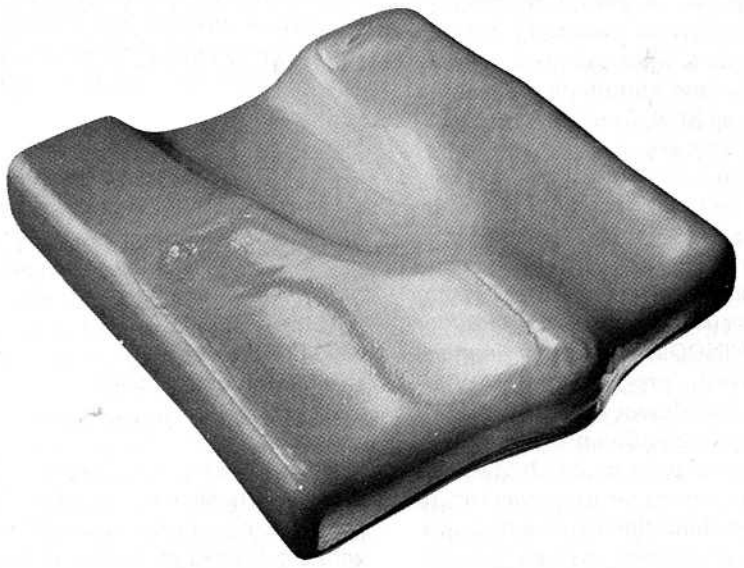

FIGURE 1.
Commercial version of the VASIO-P cushion, shown without cover.

placed on an edge-lighted transparent plate. The 0.05 inch spacing of the nubs offers a relatively high resolution means to display pressure distributions on the plantar surface. A calibration scale is provided by the application of a set of known weights creating spots of different light intensities representing 250, 500, 1000, 1500, and 2000 mm Hg pressure.

Preliminary work continued on a stump volume study. A water displacement method is used to monitor the change in volume of a postoperative lower-limb stump in order to help determine when the amputee is ready to be fitted with the first permanent prosthesis. Different stump management methods will be investigated to determine which offers the more rapid and reliable means to accelerate maturation. The objective is to reduce the incidence of stump-socket disparities and thereby extend the useful life of the first permanent prosthesis.

A normative study of normal adults is planned to develop a base reference by which to compare the biomechanic performances of patients. Using the laboratory instrumentation, normals will be asked to walk at different rates. Waveforms of joint movements, loading rates, tachograms and accelograms will be characterized as functions of stride frequency and stride length in order ultimately to compare with a patient's functional stride frequency and stride length. Additionally, the accelerometer will be used to calculate the external mechanical work of locomotion, also expected to be characterized by stride frequency and stride length.

Preliminary effort is planned for the foot interface pressure study to develop prescription criteria for interface materials and to explore techniques for objectively monitoring the healing rate of plantar ulcers.

Preliminary work planned for the stump volume study includes development of computer programming to relate stump volume to time, and to correlate stump circumference with stump volume.

Program for Evaluating and Monitoring the Dysvascular Patient

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A part of this program, initially reported in BPR 10-35, Spring, 1981, concerns the delineation of the place of lumbar sympathectomy in the management of atherosclerotic occlusive disease. Previously reported experimental work using polarographic monitoring of local hydrogen gas desaturation for measuring myocutaneous perfusion in the canine has demonstrated an increase in myocutaneous perfusion following unilateral lumbar sympathectomy with the contralateral limb being used as a control.

As part of the clinical portion of this study of lumbar sympathectomy, a retrospective analysis of 121 male patients with unilateral lumbar sympathectomy for atherosclerotic occlusive disease has been done. In each patient, the unsympathectomized contralateral limb has been used as a control. The effectiveness of lumbar sympathectomy is being analyzed using arteriography, Doppler ultrasound, external magnetic flowmetry, thermistor thermometry, and photoplethysmography. The current follow-up ranges from less than one year to more than twenty years. Data is being analyzed utilizing mortality rates and limb viability expressed in life tables.

Preliminary data indicates that lumbar sympathectomy is of value in retarding the progression of atherosclerotic occlusive disease. As an example, a 53-year-old white man with severe disabling claudication had a right lumbar sympathectomy in 1975. For 3 years the patient was without symptoms. Then he presented with right iliac artery occlusion and disabling claudication for which an aorto-bilateral femoral bypass was done. Five days after bypass, the patient's ischemic indices (ankle/brachial systolic pressure ratio) were 1.12 on the right and 1.10 on the left. Six months following the aorto-bilateral bypass, the patient presented with disabling claudication on the left side. At this time, the ischemic index on the sympathectomized right side (1.08) showed no significant change, while on the nonsympathectomized left side the ischemic index dropped to 0.59. A left profunda popliteal bypass was done. In this patient, with an aorto-bilateral femoral bypass and prior sympathectomy on the right side, normal ankle pressures were maintained, while on the left unsympathectomized side, the patient's disease process rapidly progressed to the point where additional surgical intervention was required.

A second example demonstrates the presence of a long-term effect from lumbar sympathectomy. This 56-year-old patient has a left lumbar sympathectomy and was followed for 10 years. Five years after left lumbar sympathectomy, the left ankle Doppler systolic pressure was 111 mm Hg (ischemic index: 0.68); at ten years, left ankle Doppler systolic pressure has been maintained at 110 mm Hg (ischemic index: 0.65). Similarly, at five years post sympathectomy, the patient's ankle/forehead temperature ratio was 0.98 and the toe/forehead temperature ratio was 0.97. At eight years post-sympathectomy, these temperature ratios remained unchanged. Additionally, the ankle/room temperature ratio at 5 years was 1.39 and the toe/room temperature ratio was 1.38. At 8 years, these ratios showed minimal change, being 1.31 and 1.29 respectively.

The prolonged beneficial effect of lumbar sympathectomy is demonstrated by a third patient, using the treadmill walking test. Pre-sympathectomy a 60-year-old man's ischemic index was 0.78 on the right and 0.93 on the left. Several days post-right-sympathectomy, the right ischemic index showed no significant change (0.75) while the left was 1.07. At 4 years following right lumbar sympathectomy, the right ischemic index remained at 0.75 while on the left, nonsympathectomized, side the ischemic index had significantly dropped from 1.07 to 0.59. On treadmill evaluation 1 year post-right-lumbar sympathectomy, the patient's exercise was stopped at about 7 minutes at 484 meters (2.5 mph at 12% grade) by absolute claudication on the sympathectomized right side with an 8 mm Hg drop in ankle pressure that returned to baseline in 4 minutes. At 4 years post-right-lumbar sympathectomy, the patient's exercise was stopped

at 4½ minutes at 231 meters (2.0 mph at 12% grade) by absolute claudication on the nonsympathectomized left side with a 40 mm Hg drop in ankle pressure that did not return to baseline after 11 minutes—whereas the patient's sympathectomized right side showed no pressure drop.

As there is no consensus as to whether or not lumbar sympathectomy is of benefit in the management of atherosclerotic occlusive disease, this study is aimed toward clarifying the role of lumbar sympathectomy. It is believed this study should enhance the management of the aging population which has demonstrated high incidence of atherosclerotic occlusive disease.

Clinical and Laboratory Study of Amputation

Prosthetics Research Study
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1. Limb Viability

The initial study relating transcutaneous pO_2 determination to clinical amputation healing in ischemic limbs has been completed. The results of this research will appear in the March 1982 issue of The Journal of Bone and Joint Surgery. As a result of the information obtained from measurements in 37 patients who required below-knee amputation because of peripheral vascular insufficiency, we now have incorporated the technique in the preoperative diagnostic vascular protocol as a routine, non-invasive, objective determinant. PRSC and the Limb Viability Laboratory, Department of Orthopaedics, University of Washington, are now proceeding to multi-focal measurement techniques which will simplify and shorten the time necessary to scan the ischemic limb. Data retrieval is acquired not only on patients coming to amputation for ischemia, but also for evaluation relative to vascular reconstructive surgery, the effect of such reconstructions on transcutaneous oxygen tension, and the role of conservative management. Millions of Americans including the large diabetic population are experiencing symptomatic occlusive arterial disease. The World War II veteran population is particularly at risk. Statistics on veterans hospitals across the country reflect the increasing numbers of patients coming to vascular screening, vascular reconstruction and amputation. These data bases are valuable additions to our knowledge.

2. Laser Doppler Profile.

For the past several years, we have been supporting Dr. Allan Holloway, Center for Biomedical Engineering, University of Washington, School of Medicine in the development of a uniform, non-invasive technique utilizing a laser beam coupled with the Doppler phenomenon to quantitate skin circulation. Patients with limb ischemia at VAMC Seattle were incorporated in this instrumentation and data accrual. The technique has now been standardized. Measurement results are quantified against other laboratory determinants including segmental blood pressures and transcutaneous pO_2. Measurements have been extended to patients undergoing plastic surgery, particularly microsurgical composite tissue grafting. We at PRSC are particularly enthusiastic about the diagnostic and predictive potential of this ingenious system. It incorporates the same practical features of similar research tools with which we are familiar. These qualities include (i) ease of measurement by a qualified technician, (ii) simple, painless, non-invasive probes, and (iii) portability of the equipment. As with other related laboratory systems for determining limb viability, practical application involves a large patient population within the VA system.

3. Multispectral Analysis.

We are still in the process of calibrating and standardizing multispectral analysis to measure oxygenated hemoglobin within the skin. Dr. Martin Afromowitz, our consulting research electrical engineer, together with his colleagues, has assembled a digital readout measurement device which eliminates sending photographs to one of the NASA centers for interpretation. We are at the stage of data accrual using this equipment. Originally developed for assaying the degree of tissue death and of suitability for skin coverage in human burns, we have adapted the system to study oxygen perfusion in intact ischemic skin.

4. Microwound Histopathology.

This in vivo study of healing in controlled experimentally produced micro-incised human limb wounds is yielding provocative early information on the nature of wound healing in the presence of peripheral vascular disease. The study has been approved after careful and critical review by the Veterans Administration and University Human Experimentation Committee. Its purpose is to explore the nature and/or absence of skin wound healing in limbs with peripheral vascular disease. Drs. Odland and Olerud who are analyzing the harvested tissues now plan to proceed to electron microscopy for further basic information.

These several separate but related research endeavors place us and our associates at the leading edge of limb viability research. A "Current Concepts Review" in the December 1981 issue of the Journal of Bone and Joint Surgery, written by us, summarizes our progress.

5. Research Prosthetics.

The progress of research in prosthetics coincides directly with the purpose of PRS to develop new surgical/prosthetic techniques to improve prosthetic care of the amputee through research and the development of components and techniques. The first step taken was to direct our attention toward new materials currently used in professions other than prosthetics. Requests were sent to industries for samples and technical data. The materials were divided into categories for analysis.

In addition to materials analysis, an effort was made to continue those projects already underway. Of primary importance at this time is the research and development of a high-performance foot designed specifically for running. We currently have six patients wearing this foot, and while it has been well accepted, we have had some breakage problems so we are currently reevaluating the design to improve performance.

New developments and techniques underway at PRS include the following: The use of thermoplastic adjustable sockets, directional liners, inter-

TABLE 1.
Amputation Service, Seattle—Statistics for Quarter 1, Fiscal Year 1981–82

Number of patients admitted with threatened limb:	
Infection	1
Vascular	40
Amputation surgery:	
Primary amputations	16
Failed-amputation revisions	5
Old amputation revisions	2
Opposite limb amputations	3
Physical therapy treatments:	
Inpatient	515
Output	338
Research patients seen in prosthetic clinic:	67

face materials, injectable foams and cosmetic covers.

6. Clinical-Research Amputation Service, VAMC

With the support of VA Central Office, we have now included special prosthetic problem referrals from other VA facilities for evaluation and treatment at this center. We anticipate a total caseload of approximately 125 amputations to be performed at the VAMC amputation service (Table 1) during the calendar year 1982. These patients, together with the established amputees seen in our weekly clinics and referred from other VA services, form the basis for our continuing clinical research to improve wound healing and functional restoration and prosthetic rehabilitation.

Comprehensive Management of Upper and Lower Extremity Amputation

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The major scope of our program is a continuing evaluation of immediate postoperative fitting for upper and lower extremity amputees, with emphasis on rapid rehabilitation and improvements in patient function.

Since the last report, we have been continuing to provide care for both upper and lower extremity amputees. We have been involved in upgrading a variety of prosthetic components to meet specialized needs for our patients, including recreational and occupational activities.

We currently plan to expand our program in both scope and personnel, contingent upon the availability of funding.

Transcutaneous Oxygen Tension as Predictor of Wound Healing

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Prosthetics Research Study
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Ernest M. Burgess, M.D.

This study is directed at evaluating the use of transcutaneous oxygen tension as a means of assessing peripheral circulation in patients with peripheral vascular disease (1). For several years we have been accumulating evidence which indicates that transcutaneous oxygen tension is a sensitive indicator of the healing potential of skin at the measurement site on the extremities of patients with peripheral vascular disease. For example, an amputation performed through a site where transcutaneous oxygen tension is low (less than 20 mm Hg) is extremely unlikely to heal (2).

Over the past year, we have been expanding our measurements of transcutaneous oxygen tension on patients with mild to very severe peripheral vascular disease. We now have over 250 complete transcutaneous oxygen tension profiles on the limbs of over 190 patients. As reported previously, transcutaneous oxygen tension continues to be a highly accurate prospective predictor of amputation success or failure. In addition, we have found that a very low transcutaneous oxygen tension (less than 10 mm Hg) at the foot prior to a vascular reconstruction is highly correlated with no improvement in clinical status (e.g., the patient goes on to an amputation) irrespective of whether the reconstruction remains patent. If transcutaneous oxygen tension is moderate to high before a vascular reconstruction, then the post-reconstruction transcutaneous oxygen tension is significantly correlated with the clinical success or failure of the reconstruction. In patients with mild peripheral vascular disease (i.e., intermittent claudication), we have found that transcutaneous oxygen tension on the lower leg correlates extremely well with ankle Doppler pressures during recovery from treadmill exercise. Our results to date indicate that transcutaneous oxygen tension is a valid indicator of circulatory adequacy in patients with diabetes, as well as those without diabetes. A report covering these findings is being prepared.

New multiprobe monitor

Within the next month, we will begin testing a multiprobe transcutaneous oxygen tension monitor developed in collaboration with the Department of Electrical Engineering at the University of Washington. This device will allow us to make simultaneous measurements at a number of sites in order to map out the circulatory status of an extremity or a potential amputation site. We also will use this device to examine the reflex reactivity of skin at different local temperatures in a study designed to examine the basic physiology behind the measurement of transcutaneous oxygen. Finally, we are conducting preliminary studies designed

to examine how transcutaneous oxygen tension correlates with the healing of small wounds made on patients who are scheduled for amputation.

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Prosthetics Research

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Below-Knee Preparatory Prostheses

The purpose of this project is to develop a cost-effective preparatory prosthetic system for rehabilitation management of the BK amputee, to refine a standardized alignment system for the BK prosthesis, and to develop a reliable direct-forming casting procedure for BK-level amputations.

A simple, lightweight preparatory BK prosthesis has been fabricated from Scotchcast® 3M casting tape and polyvinyl chloride tubing. A simplified but accurate alignment technique is being used. The soft insert has been replaced with an athletic-type tube sock.

Patients have been fitted with the system with good acceptance and minimal adjustments.

The next step is to finalize the fabrication of the preparatory system, and to develop patient evaluation forms and data collection sheets to record the total prosthetic management time, frequency of adjustments needed to accommodate residual limb changes, and the alignment changes.

Future plans also include development of a Syme's preparatory prosthesis, on which work has begun, further investigation of the alignment system, and continued efforts for directing vacuum forming of the socket to the patient's residual limb.

Powered Arm for Shoulder Disarticulation Levels

Development of a total arm prosthesis for shoulder disarticulation amputees, which utilizes unbeatable position-servo control by shoulder motion, is also continuing. An experimental prosthesis has been built to evaluate unbeatable position-servo control in this application. The unbeatable control is achieved by direct cable linkages between a shoulder motion transducer and the prosthesis actuators. Control signals are derived from strain gages incorporated in the cable linkages. Forces produced by attempted motion of the shoulder cause the prosthesis actuators to respond in some predetermined manner so as to maintain a fixed level of force in the cable links. The response of the prosthesis allows the shoulder to move, maintaining an intimate relationship between the position of the prosthesis components and the shoulder.

The actuators used in the experimental prosthesis have been the Northwestern University wrist rotator and the Liberty Mutual/Boston elbow.

The ability of non-amputees to control the experimental prosthesis with shoulder motion has been demonstrated. Experiments were conducted to compare prosthesis control with control of the intact arm and shoulder. The results of this work have been published as a doctoral dissertation (2).

Control of the experimental prosthesis by non-amputees was sufficiently good to warrant further work to produce a prosthesis to be used by an amputee on an experimental basis. Efforts are currently directed at redesigning the prosthesis control and harnessing system so that it will be acceptable to an amputee and able to survive the rigors of daily use. The redesign will involve three principal areas: (i) mounting and encapsulating the force transducers to protect them from environmental damage, (ii) redesign of the electronic circuits used to monitor the transducers, to eliminate temperature sensitivity and to provide long-term stability with low power consumption, and (iii) design and fabrication of a harnessing system that the amputee can don and doff without assistance.

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Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Work continues in examination of the physiologic suspension and stability which exist in the below-knee prosthesis by virtue of the active stump musculature.

The purpose of this work is to gain a better understanding of the parameters by which the prosthesis and the stump can provide the amputee with maximum stability, comfort and proprioception. During this reporting period, improvement has been made in the contour measurement with a mechanical device which converts stump contours into a contour plot on the X-Y recorder. In this report the refined methods of measurement and analysis on nine limbs of six patients will be described and illustrated.

Methods

1. Measurement of all below-knee amputee patients who are ambulatory in their prostheses (and without skin problems) at the Seattle VA Hospital and Medical Center Prosthetics Clinic.
2. Application of the protocol to residual limbs resulting from both conventional and myoplastic techniques of amputation surgery.
3. Evaluation consisting of residual limb and socket measurements plus a static prosthesis suspension evaluation. Also, a tracing is made

of the contours of the external residual limb (surface and sub-surface) and the internal contours of the prosthetic socket (Fig. 1).

4. A notation of the location, degree, and contour of the residual limb's muscle bulges and their relationship to the external contours of the limb (Fig. 2).
5. Observation of how the stump musculature contours interact with the internal contours of the socket, and whether they relate congruously or incongruously. When congruous, a muscle expands into a similarly shaped contour within the socket (Figs. 3, 4, 5). The graphs (force retention curves) show how each prosthesis and residual limb interact in tensile loading (Figs. 3, 4, 5). Steep curves indicate a high degree of suspension stiffness (large suspension force with minimal pistoning, yet negligible risk of constriction when relaced). Shallow curves indicate poor suspension. The dashed horizontal line represents the weight of the prosthesis. A curve which does not intersect this line indicates that the patient cannot generate sufficient force to lift the weight of the prosthesis (Fig. 4).

The factors for residual limb and socket suspension which we derive from our evaluations are listed in Appendix A. The parameters by which suspension performance is defined are listed in Appendix B. A mathematical regression analysis correlates suspension performance with measured suspension factors.

Results

The subject population is too small to perform a statistically significant multiple regression analysis. Covariance analysis has, however, delineated the following relationships. A statistically significant correlation between the prosthesis pistoning measurement and the mediolateral socket contour has been found. A significant correlation between the maximum retention force measurement, and the mediolateral muscle contour and compliance measurements was also found:

($R=-0.732$ $P=0.039$ / $R=-0.695$ $P=0.037$ / $R=0.771$ $P=0.015$ (respectively)).

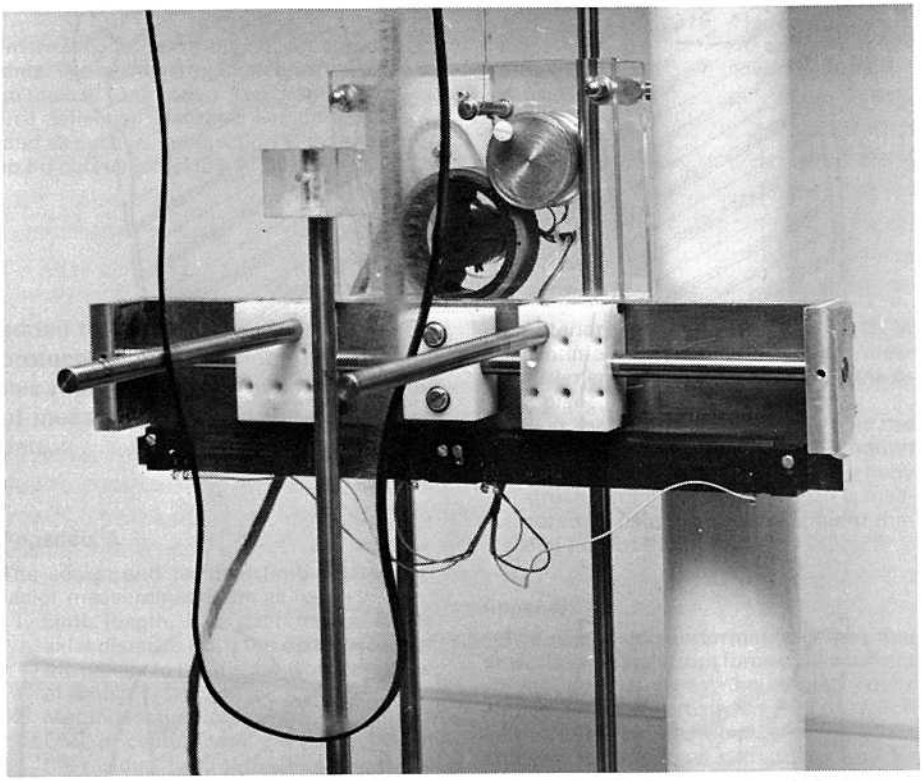


FIGURE 1
The contour replication device produces a tracing of limb and socket contours. As the carriage travels downward two rods follow the surface contours of the stump or are manually pressed inward to follow the firmer bone and muscle contours. Axial, medial, and lateral signals are thus produced.

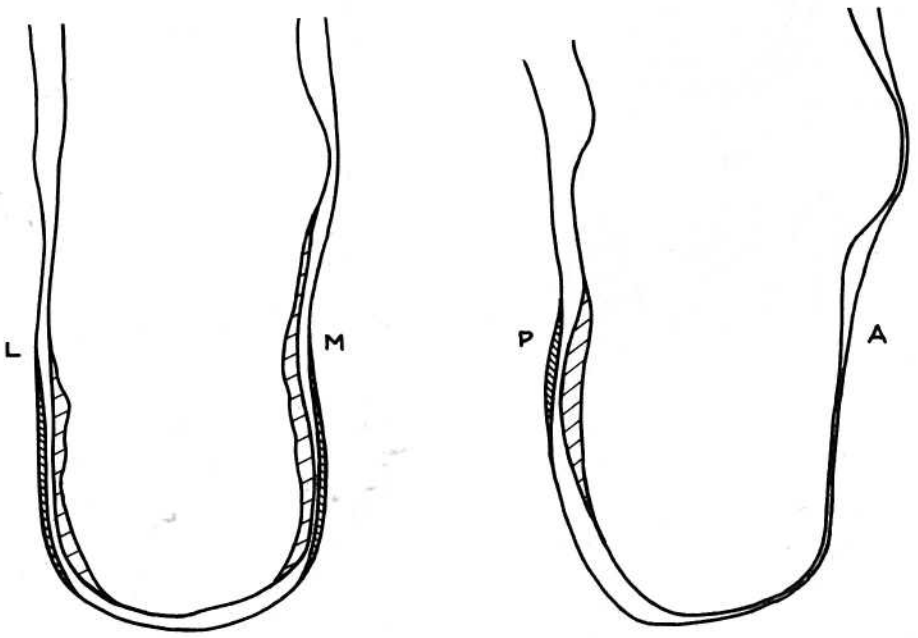
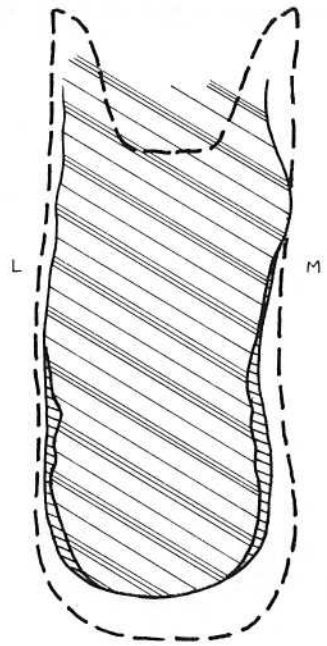


FIGURE 2
These profiles show the relationship between the surface contours of the residual limb and the firmer, sub-surface bone and muscle contours. The cross hatched areas represent the contour, degree, and location of the muscle bulges.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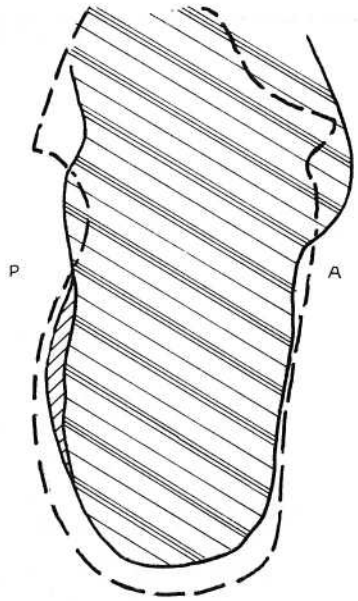
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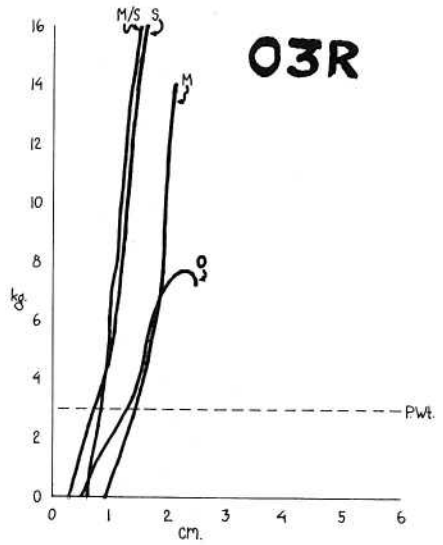
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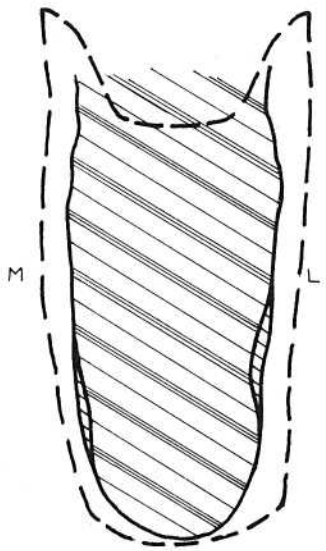
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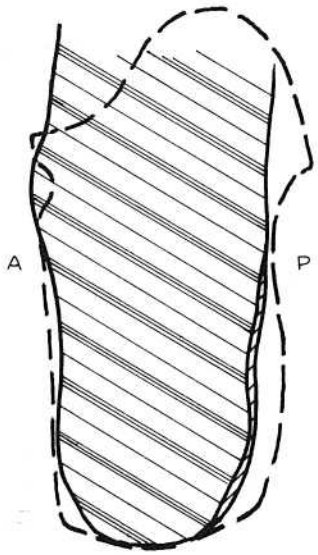
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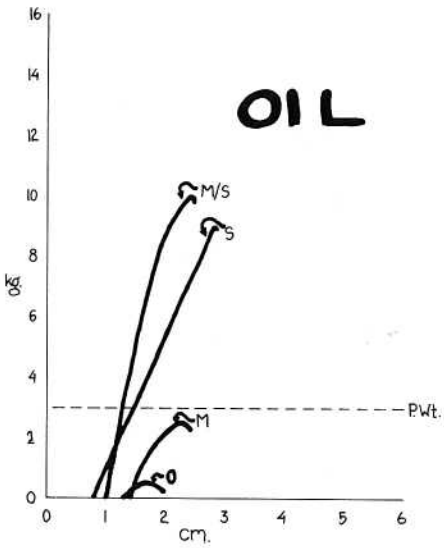
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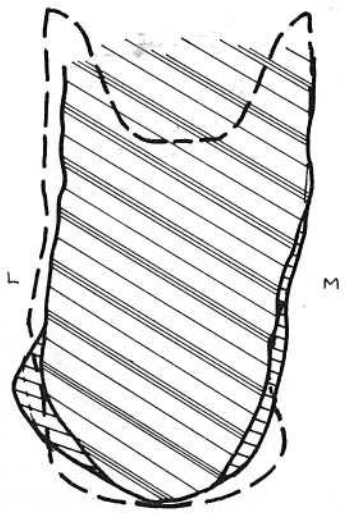
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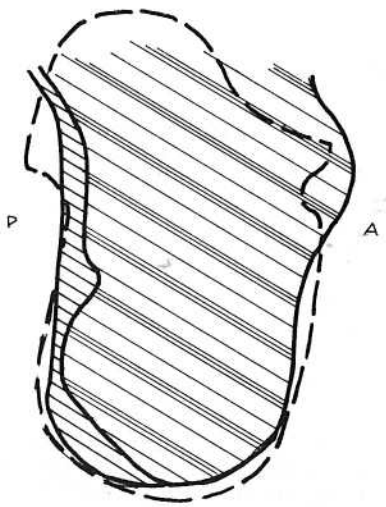
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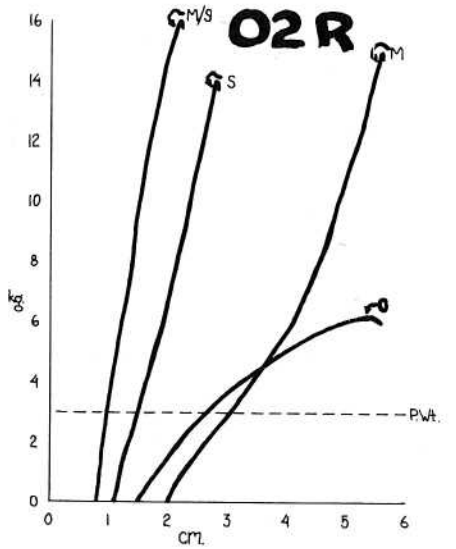
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FIGURES 3, 4, 5 (opposite)
These profiles show the relationship between the internal contours of the socket and the surface contours of the residual limb for various patients. The narrow irregular crosshatched area indicates in each profile the contour change from muscle contraction. The graph which appears at the right of each pair of profiles is a force deflection diagram. The horizontal dashed line indicates the weight of that prosthesis, and as such its intersection with the f-d curves is an indication of prosthesis pistoning. Steep f-d curves indicate a high stiffness in the interface and therefore good suspension.

NOTE: Figures 6, 7, 8, 9 & 10 are on the following pages.

The data also showed improvement in the amount of tensile force produced when the stump musculature was active, and a decrease in prosthesis slippage even when the existing suspension was attached. An axial cushioning component was also produced by the active stump musculature (Figs. 6, 7, 8, 9).

The data indicated that stump length was not a significant predictor of suspension characteristics. Interference was significant only secondarily to socket contour. In other words, a high degree of interference between the muscle bulges and the contours of the prosthetic socket would produce ejection in a tapered socket but would augment suspension if the socket was flared distally.

Of particular interest in this population was patient 03R, who had the best suspension. In this case the contours of the residual limb's muscle bulges and the contours of the internal socket can be seen to have mated in a congruous way (Fig. 3). Also of interest was patient O1L who had the worst suspension, and patient 02L, who had the highest level of stump-musculature activity but had unremarkable suspension due to parameters of fit (Figs. 3, 4 and 5, respectively).

Results in this reporting period continue to support the initial hypothesis that physiologic suspension is a function of stump firmness, stump and socket contour, interference, and skin motion. It appears that stump and socket contour in the mediolateral plane, and the firmness of the contracted stump-musculature, correlate most highly with the indicators of suspension performance.

Evaluation of the effects of an isometric socket-retention exercise program is planned next. This program is expected to improve suspension performance.

Use of stump volume measurement device reported upon earlier will be added to the analysis. Refinements in protocols and equipment described in this report have improved the quality of measurements and the analysis of data.

Appendix A

The socket and residual limb suspension factor measurements are as follows:

1. Limb length, L in centimeters, is the axial distance from the distal aspect of the patella to the distal tip of the residual limb.
2. Mediolateral dimensions, KML and DML in centimeters, are the widths of the residual limb at the knee and at the distal m-1 muscle bulge, respectively.
3. Residual limb taper, T, is equal to one minus the ratio of the KML to the DML. This is positive for bulbous stumps and negative for tapered stumps.
4. Mediolateral expansion, E in centimeters, is the increase in the DML dimension generated by contraction of the residual limb muscle mass.
5. Compliance, F in centimeters, is the amount of compression induced when the contracted muscles at the point of the expansion measurement are subjected to a given compressive force. The amount of compression is inversely proportional to the firmness of the contracted musculature.
6. Mediolateral muscle contour, C1 in degrees, is the amount of the maximum bulge of the contracted musculature in the area of the expansion measurement. A positive value indicates muscle contours potentially advantageous to suspension.
7. Mediolateral socket contour, C2 in degrees, is identical to the C1 measurement except that it is made of the internal contours of the socket.
8. Mediolateral interference, I1 in cm., is the difference between the DML dimensions of the socket (minus the thickness of the interface) and of the residual limb. A negative value indicates looseness.
9. Anterior-posterior muscle contour, C3 in degrees, is identical to the C1 measurement except that it is taken in the A-P plane through the point of maximum contracted muscle bulge.
10. Anterior posterior socket contour, C4 in degrees, relates to the C3 measurement in the same way as C2 relates to C1, except that it is in the A-P plane.
11. Anterior-posterior interference, I2 in centimeters, is identical to the I1 measurement except that it is taken in the A-P plane.
12. Skin motion, M in centimeters, is the maximum amount of vertical motion possible between the skin and the bony structure of the residual limb. It is measured by palpation on the anterior medial face of the tibia.

Appendix B

The suspension performance of the prosthesis is evaluated from force-displacement curves generated as the subject pulls straight up on the prosthesis with the residual limb. These recordings are taken with and without volitional stump musculature activity and with and without the existing suspension attached. The following indicators are measured in the case where the existing suspension is detached and the musculature is contracted.

1. Prosthesis pistoning, P in centimeters, is the displacement undergone between the prosthesis and the residual limb from the point of equal weight bearing to the point where the tensile force exerted by the amputee is equal to the weight of the prosthesis. ($\bar{P}$ = 2.5 cm.)
2. Maximum retention force, R in Newtons, is an indication of how the muscle contours interact with the contours of the socket in their most advantageous position. This force occurs after a displacement of approximately 3 cm. $\bar{R}$ = 88 N@$\bar{P}$ = 3.8 cm. # of subjects = 9.
3. Suspension stiffness, S in Newtons per centimeter, is a measure of the effectiveness of the interface between the prosthesis and the residual limb. This factor is measured at the point where the retention force goes from weight-bearing to tensile.

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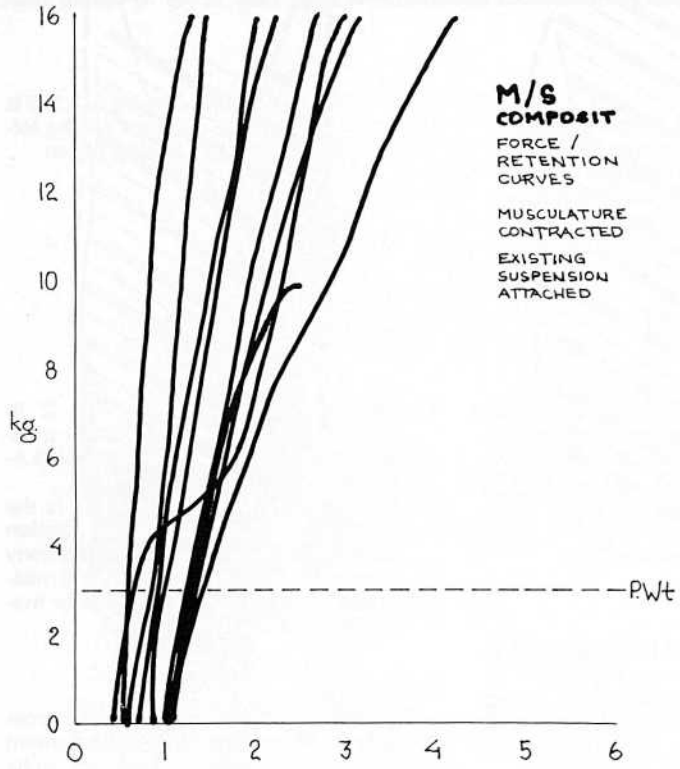


FIGURE 6.

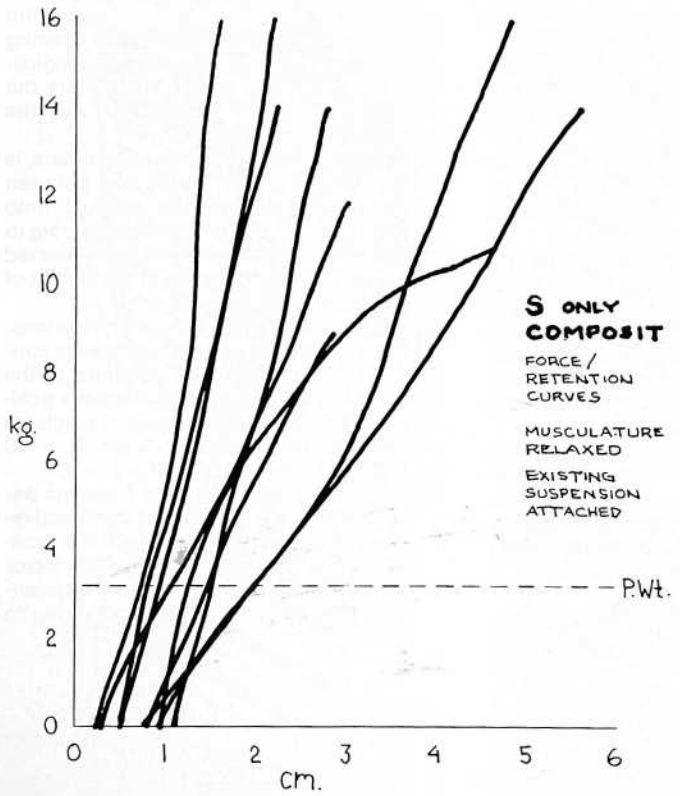
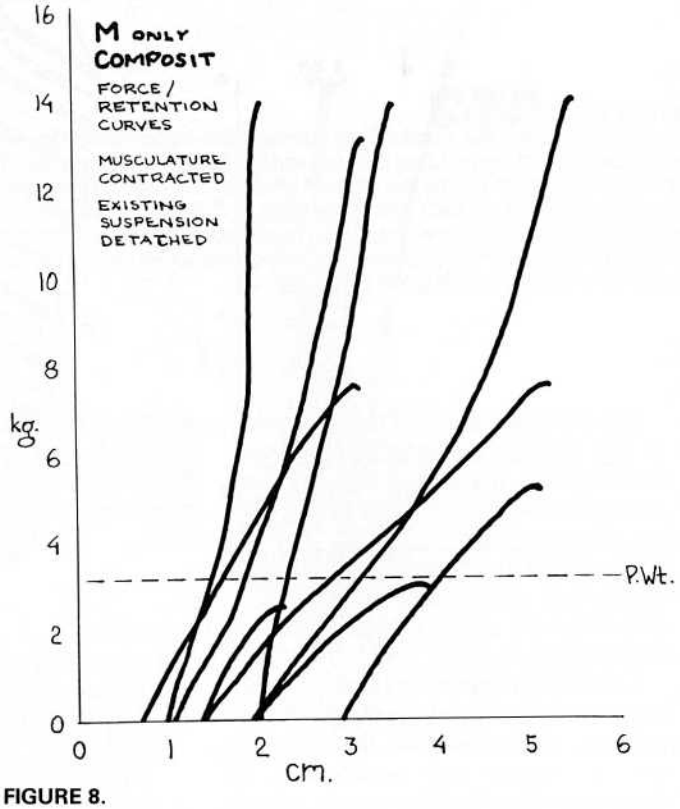


FIGURE 7.

These figures are composite force-displacement curves for the present population of completely evaluated patients. Figure 6 (top) represents data obtained with musculature contracted and existing suspension attached: Figure 7 (above) represents data obtained with musculature relaxed and existing suspension attached.



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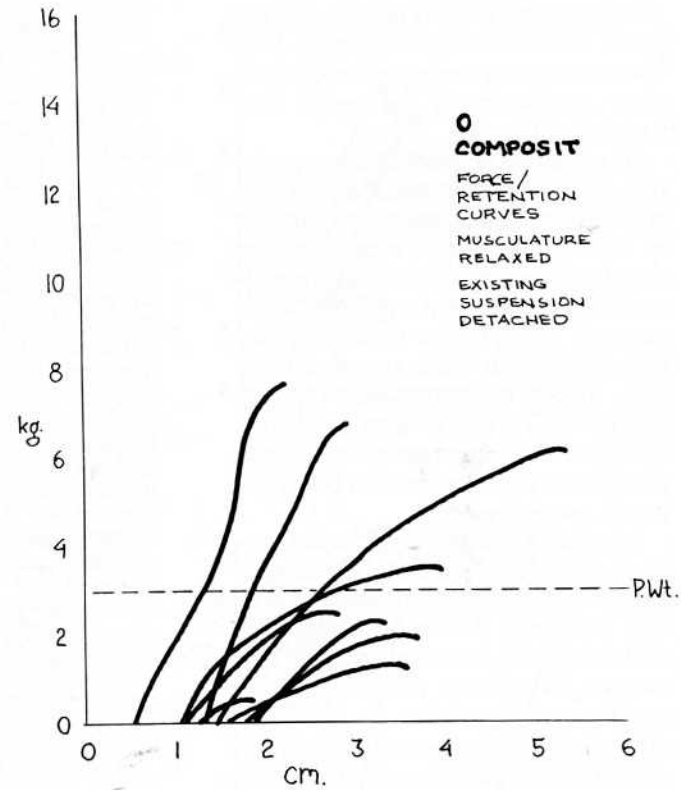

FIGURE 9.

These figures are composite force-displacement curves for the present population of completely evaluated patients. Figure 8 (top) represents data obtained with musculature contracted and existing suspension detached; Figure 9 (above) represents data obtained with musculature relaxed and existing suspension detached.

FIGURE 10
Summary of suspension factors and performance indicators.

		A	B	1	2	3	4	5	6	7	8	9	10	11
		P	R	L	1	E	F	I1	C1	C2 SKT	I2	C3 B	C4 SKT	M
		to P.W.	Max.F	L	T(ml)	EXP	F	INT(ml)	T(ml)	T(ml)	INT(AP)	T(AP)	T(AP)	SKIN
		cm.	kg.	cm.		mm.	mm.	mm.	o	o	mm.	o	o	cm.
03R	G.Q.(R)	1.4	137	20	+.04	+ 4	- 9	+ 3	+15°	+ 7°	+13	+15°	+15°	1.9
02L	L.B.(L)	1.5	69	8	-.03	+ 5	-10	+11	+ 5°	- 1°	+26	- 5°	0°	2.9
03L	G.Q.(L)	2.0	127	15	+.09	+ 6	-11	- 4	+15°	+15°	+18	0°	+20	2.3
05R	M.K.(R)	2.3	137	16	-.16	+ 6	-11	- 3	- 5°	+ 5°	0	+ 5°	- 5°	3.5
06L	R.R.(L)	2.7	69	16	-.14	+ 3	- 5	+ 5	- 5°	-10°	+ 2	+ 5°	0°	1.4
02R	L.B.(R)	3.0	147	13	-.08	+18	-25	+25	+15°	-15°	+20	0°	+10°	2.0
04L	B.G.(L)	3.9	49	13	-.13	0	- 2	+15	- 5°	-30°	+ 5	-10°	+ 5°	2.4
04R	B.G.(R)	3.9	29	16	-.13	+ 2	- 5	+12	- 5°	- 5°	+ 8	0°	+ 5°	2.4
01L	H.H.(L)	4.0	25	14	-.11	+ 5	- 7	0	-15°	-15°	+ 8	0°	+ 5°	1.8

A Grommet Bone Liner for Flexible Implant Arthroplasty

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Alfred B. Swanson, M.D.

This is a 3-year research project which is developing an interpositional device to be placed between bone and silicone elastomer implants.

The project has proceeded through the evaluation of materials and designs, and a metal grommet has been selected. Animal studies have been completed, with early data indicating that the device is suited for clinical study.

The third year of the research project was for the clinical study in a group of patients. Completion of the clinical research has been impeded by the administration's budget cuts, which caused the VA contracts to be withdrawn. Clinical studies will be conducted as alternative funds are found.

In Vivo and In Vitro Studies on Rat Bone Structure and Material Properties

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Richard Lee, B.A.
Dennis R. Carter, Ph.D.
David J. Baylink, M.D.

The purpose of this research is to elucidate the effect of animal age and activity on the structural, geometric, and material properties of rat long bones. The effects of diets which induce osteomalacia, osteoporosis, and osteolathyrism are also being examined. An in vivo strain gage implantation procedure (1) and several in vitro mechanical testing techniques (2) have been developed. Bone cross-sectional properties are determined using a computerized numerical procedure (3).

Approximately 100 Sprague-Dawley rats ranging in age from 21 days have been examined. The animals received either no activity (caged controls-group 1), or were forced to run in exercise wheels for 0.02 kilometers/day (group 2) or 0.5 kilometers/day (group 3). Results indicate that changes in the structural properties of the rat femora cease at an age of approximately 110 days. From an age of 21 to 110 days the torsional strength (T) increased 1650% for groups 1 and 2, a 150% greater increase than that for group 3. Torsion stiffness (GK) increased 1000% for groups 1 and 2, a 230% greater increase than that for group 3. The increase in structural properties was caused by both geometrical and material property changes in the bones.

Over the age range examined, the shear strength (τ) of the bone tissue increased by approximately a factor of 3 and the shear modulus (G) increased by a factor of 2 for all groups, indicating that exercise has little or no effect upon bone material properties. Log-log plots of T, K, GK and τ versus bone length, animal age, or weight revealed allometric relationships ($y = ax^b$) which indicate that bone geometry and material are being regulated to optimize structural properties.

Non-stress exercise experiments, in which the animals (rats) run in specially designed exercise wheel-cages, and diet (osteolathyrism) studies are currently being investigated. The geometric, structural, material and fatigue properties of primate (Nemestrina) long bones will also be evaluated in

the near future. Techniques for investigation of bone microstructure (bone mineral and collagen) are also being developed.

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Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials: A Pilot Study

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Wendell Williams, Ph. D.

The overall goal of this project is to develop new techniques applicable to electrical stimulation of repair of those fractures, osteotomies, and nonunions in which surgical intervention for structural bone transplantation and/or internal fixation is indicated.

Work in the current period was divided into two main parts, as planned originally: (i) evaluation of Osteostim™ implantable bone-growth stimulators (S12 model)—completed in 1981; (ii) evaluation of techniques for bone stimulation by implantation of piezoelectric materials—in progress at present.

At the time this investigation began, the Osteostim S12 stimulator, developed by Patterson in Australia, had just been introduced into the USA commercially and was being recommended for use in treatment of nonunions, bone defects, and other purposes. It was felt that this totally implantable unit might be well suited to the needs of VA patients and deserved evaluation. Another manufacturer recently has taken over this unit.

The Telectronics type stimulators were utilized to study healing in two types of defect in canine distal ulna. In one type, a 1.5-cm segment of bone was removed and the cathode coiled in the defect. In a second type, the 1.5-cm segment was drilled and replaced as a segment being threaded on the cathode wire. Animals were sacrificed for study at 8 weeks.

While these experiments were not entirely satisfactory due to technical difficulties, the overall impression in both the bone defect and bone transplant models was that the d.c. stimulation did not have a major effect on the healing pattern. In both models, there was variation in the overall pattern seen, but no obvious preponderance of new bone formation or increased remodeling activity on the stimulated side. Furthermore, at 8 weeks, no consistent differences were noted between those stimulated the full 8 weeks and those in whom stimulation ceased at 1–4 weeks due to breakage of equipment.

Several comments may be of interest on our experience.

1. In all cases, stimulation was started on Day 1 of surgery. Therefore, the model is not strictly comparable to adding stimulation to an existing nonunion or earlier transplant.

2. In all cases, the cathode location was essentially devoid of preexisting living bone cells. The results tend to confirm the principal investigator's impression from earlier experience that direct electrical stimulation is ineffective unless the cathode lies adjacent to living bone. Again, this situation was different from what might exist when treating a non-union.

3. The S12 stimulator as first employed had serious defects due to lead fragility. It is probable that the company incorporated our experience into another model which uses the case as an anode, while the cathode wire exits as a coiled stainless steel lead through a stress-relieved area and then is bonded, more distally, to the titanium lead. We had considerable discussion with them on our problems. This unit is now produced by another manufacturer.

This work was begun with preliminary animal experiments in 1981 and is currently in progress.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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John W. Schaffer, M.D.

Since the beginning of this award April 1, 1981, we have made progress in both sections of the grant. The initial section deals with 45 canine orthotopically placed vascularized ulnar transplants, with the contralateral forelimb control being performed nonvascularized. A second section of the grant deals with 45 vascularized tibia transplants orthotopically placed with the contralateral limb done nonvascularized as a control. Bone blood flow is to be evaluated after microvascular anastomosis using hydrogen washout. Nine animals in each section will be studied at 1 week, 9 at 6 weeks, 9 at 3 months, 9 at 6 months, and 9 at 1 year. All specimens will be stress tested in the biomechanics laboratory by Dr. Dwight Davy. Flow assessment will be performed, at the beginning of the experiment after microvascular anastomosis and at the time of sacrifice, using hydrogen washout techniques. Scans are proposed to be done early. Fluorochrome labeling using, among other labels, tetracycline will permit us to evaluate metabolic kinetics. Bone histology will be performed at sacrifice, using both H+E staining of decalcified bone and the fluorescence microscope study of frozen sections to permit us to evaluate the fluorescence of the fluorochrome labels.

In section I of the grant, 16 animals have been studied. Fourteen procedures have been successful with restoration of flow to the vascularized ulna transplant. These animals are currently under evaluation with 9 to be sacrificed 1 year from the experiment and 5 to be sacrificed 6 months from the experiment. Two of the 16 animals were not entered into the protocol. One of those animals died intraoperatively of anesthetic complications, and a second had to be disqualified when the primary investigator tore the vascularized pedicle at the termination of the procedure. All animals that have been kept in the protocol have thrived, feeding well, and regaining normal ambulation within one week of surgery. They have been protected postoperatively

using plaster for external support of both forelimbs for about 1 week.

In the second section of the grant, we have studied 3 canine hindlimb bone-vascularized transplants. We have found that the animals are mobilized less rapidly following hindlimb surgery compared to the forelimb procedures at this point in our work. We have not obtained any stress testing data of these animals to date. This will become available following autopsies. We do not have any tissue for histological analysis again because our protocol is in progress.

We do not anticipate any difficulty completing the grant as listed in the methods section completing all 90 procedures during the 3-year period of time.

Development of Hindfoot Joint Resurfacing Prosthesis

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The purpose of this project is to design and evaluate resurfacing prostheses for the talonavicular, subtalar, and calcaneocuboid joints, employing established prosthetic materials and fixation methods.

Previous efforts in this project have included (i) determination of normal talonavicular joint surface anatomy and comparison of this anatomy with a prototype resurfacing prosthesis (I); (ii) development of a talar resurfacing component equipped with a fiber optics force transducer for determination of talonavicular joint forces as a function of tibial load and foot position in cadaver specimens (2,3,4); and (iii) determination of compressive strength and stiffness of talar and navicular surfaces prepared to receive prosthetic components (3).

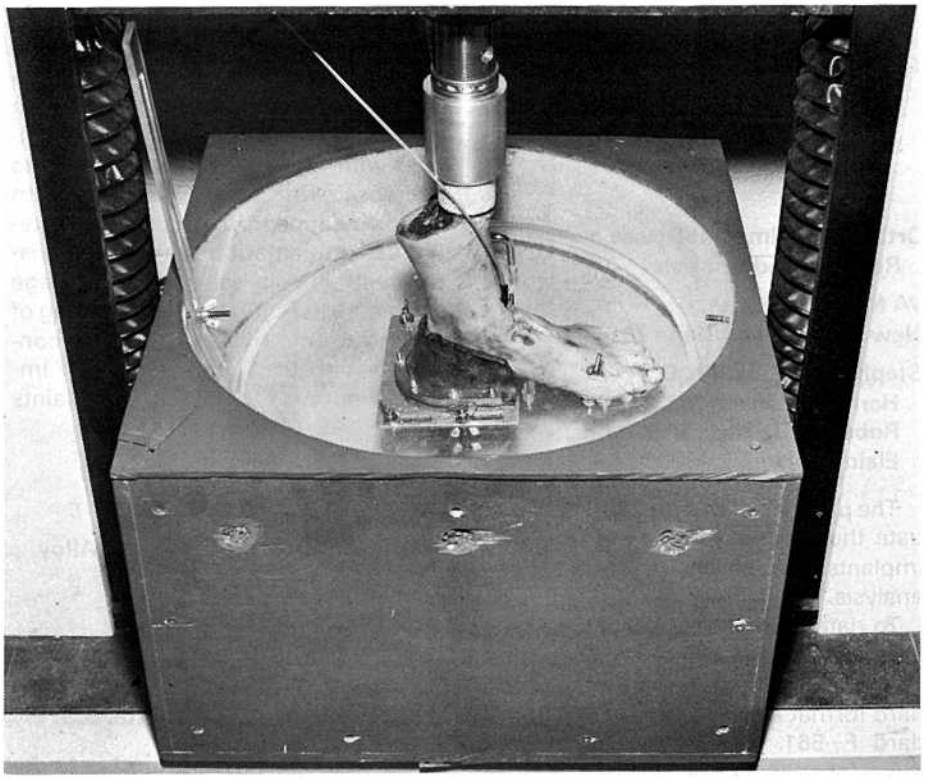

FIGURE 1.
Foot positioning apparatus allowing plantar flexion or dorsiflexion with varus or valgus.

During the period reported here the talar component force transducer has been employed in seven full-scale experiments. Loads across the prosthetic joint were determined as a function of applied tibial loads (up to 150 kgf) and foot position relative to the tibia, including various combinations of dorsiflexion (to 20 deg), plantar flexion (to 30 deg), varus (to 20 deg) and valgus (to 10 deg).

Maximum talonavicular loads were registered at 30 deg plantar flexion with 10 deg varus and were generally about 60 percent of applied tibial load. Minimum loads were registered at a combination of 20 deg dorsiflexion and 20 deg varus and were about 13 percent of applied tibial loads.

For the experiments described it was necessary to construct a special apparatus for positioning the foot (Fig. 1). As shown, the foot was placed on a circular platform. In turn the platform rode within a rigidly supported hemisphere. Within its range of travel, it could be locked in any selected position of plantar or dorsiflexion optionally combined with varus or valgus positioning. A paper describing this work is in preparation.

Recently a new study has been initiated to design subtalar joint prosthetic components. As a first step, quantitative surface anatomy of this joint is being determined in a manner similar to that employed in this laboratory for the talonavicular joint (1).

In addition, efforts are continuing to measure forces in the ligaments about the ankle and hindfoot as previously described (4). The eventual purpose is to determine how normal ligament force distribution is altered by the presence of prosthetic components.

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Orthopaedic Implant Device Retrieval and Analysis

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The purpose of this project is to evaluate the performance of orthopaedic implants through device retrieval and analysis.

To date, a total of 1,375 patient records (cases) have been entered into our computer system utilizing a standard format equivalent to ASTM Standard F–561. These may be broken down into different devices as follows:

Hips	578
Knees	132
Rods	107
Plates	126
Screws	125
Pins	47
Hip Nail Plates	224
Other	36

Recently, a study of internal fixation devices was undertaken to determine (i) whether they are being used in a temporary fashion or left in as permanent implants, (ii) whether the devices being used are performing satisfactorily, and (iii) the significance of the interface crevice corrosion that occurs between screw and plate. A total of 314 internal fixation devices (207 hip nails, 107 bone plates) were studied.

Fifty-seven of the bone plates have been removed to date (53%). Of these, 32 were classified as routine asymptomatic removals while the remainder were associated with patient complaints. Forty-four hip nails have also been removed (21%). Among these only five were classified as asymptomatic removals and eight implants were found to have fractured. Our study indicates that although bone plates are removed during the routine care of the patient, hip nail plates are being left in the patient as permanent implants, with removal only for patient complaint. The interface corrosion of the internal fixation devices was found to be independent of the length of time in vivo; however, tissue reaction associated with the corrosion was found to decrease with time. The maximum corrosion appears to occur immediately after implantation which is consistent with the initial surface damage caused at insertion by the tightening of the screw onto the plate and also consistent with the large number of implants removed for patient complaints within 2 years after implantation.

The Mechanical Properties of Porous Coated Orthopaedic Alloy

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The purpose of this project is to determine the fatigue properties of porous coated and uncoated orthopaedic alloys.

The fatigue properties of porous coated and uncoated Co-Cr-Mo alloy and titanium alloy are being determined. Samples are being tested in reverse bending using available R. R. Moore fatigue machines. Samples are being tested in air and physiologic saline. Each test is conducted to 5×10^7 cycles or failure, whichever occurs sooner, at a rate of 14,000 reversals per minute. The results of the fatigue tests are being analyzed using log-normal distribution for the generation of S-N curves and Weibull statistics to predict failure rates at given stress levels. In addition, Halperin's U_H statistical test is being applied to the data to determine whether or not a difference exists between the porous coated and uncoated samples, and between the samples tested in air and saline. The data generated to date indicate an endurance limit of 84,000 psi for the uncoated titanium alloy samples. No statistically significant difference was observed in the endurance limits of titanium samples tested in air and in saline.

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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The purpose of this project is to characterize the host response to a variety of potentially medically important biomaterials and their modifications, with respect to magnitude of response and changing cell populations in the inflammatory reaction in relation to time, and the effects on this response of therapeutic modulations to the host.

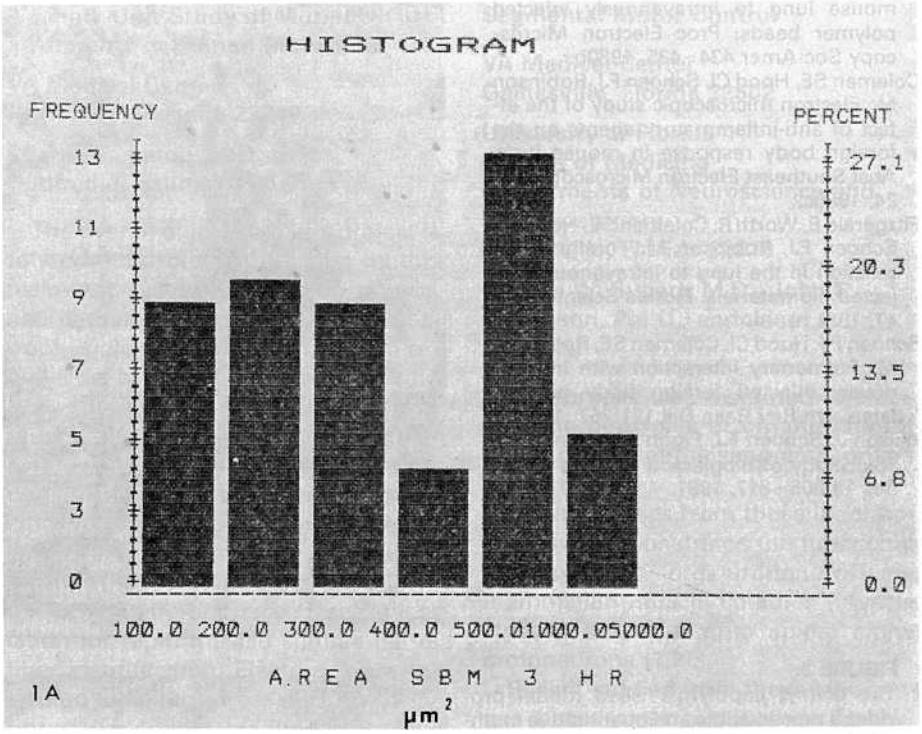
Previous work on this project has been devoted to characterization of a standard model for the foreign body reaction in mouse lung to divinyl copolymer beads as functions of time and size (surface area) as a base-line model for evaluating the host reaction to a variety of medically important biomaterials, of which we have tested silica, alumina, poly d l-lactide and Bioglasses, and for measuring the effectiveness of different types of anti-inflammatory drugs (Coleman et al., 1980a 1980b; Schoen et al., 1980; Wilson et al., 1981).

During the period July 1 – December 31, 1981, work on the quantitation of the foreign body response in relation to time and surface area was completed (Coleman et al., 1981; Fitzgerald et al., 1981). A reliable system was developed whereby the areas of granulomas formed at various times after injection of beads were measured with a digitizer and analyzed statistically with a microcomputer. This was performed for 3 size ranges of beads: 30–45, 45–53, and 53–70 micrometers in diameter. The computer-derived histograms of measurements of granuloma area at 3 hours (Fig. Ia) and at 48 hours (Fig. Ib) after injection of 45–53 micrometer beads are shown. Using the foreign body reaction to 45–53 micrometer divinyl copolymer beads as a reproducible, quantitative standard test system, the relative effectiveness of the anti-inflammatory drugs acetylsalicylic acid, polyanetholsulfonate, ellagic

acid, hydrocortisone acetate, bacterial levan (prepared from Erwinia herbicola) and azathiaprine have been tested (Fig. 2) and the evaluation of indomethacin and aminophylline are in progress. The most effective of the drugs tested to date have been azathioprine, bacterial levan, and hydrocortisone acetate which reduced the mean area of the granulomas by as much as 92 percent (Coleman et al., 1980c).

Within the last 3 months, we have begun an electron microscopic study of the ultrastructure of early granuloma formation. Methodology has been developed that permits the isolation of intact granulomas and contiguous lung so that thin sections of entire granulomas and the surrounding lung can be examined efficiently and the cellular populations and reactions involved in the dynamic process of inflammation may be observed at high magnification and at well defined early stages of the foreign body reaction (Fig. 3).

Presently nearing completion are the last of the studies of the effectiveness of anti-inflammatory drugs using the reaction to 45–53 micrometer diameter copolymer beads as a standard and quantitative model for evaluating the reduction of granuloma size by the action of the drugs after set periods of time. Experiments are also continuing, with the cooperation of the Southern Research Institute, on the reaction to poly d l-lactide beads which have been developed for drug transport. We have already found in the first series of experiments that the inflammatory response to this material is less at all time periods than that in the standard control system of divinyl copolymer beads. We have initiated studies on the inflammatory response to various known chemical formulations of the biologically important Bioglasses developed by and in cooperation with Dr. L. L. Hench of the Department of Materials Science at the University of Florida and Dr. F. J. Schoen of Harvard University (Wilson et al., 1981).



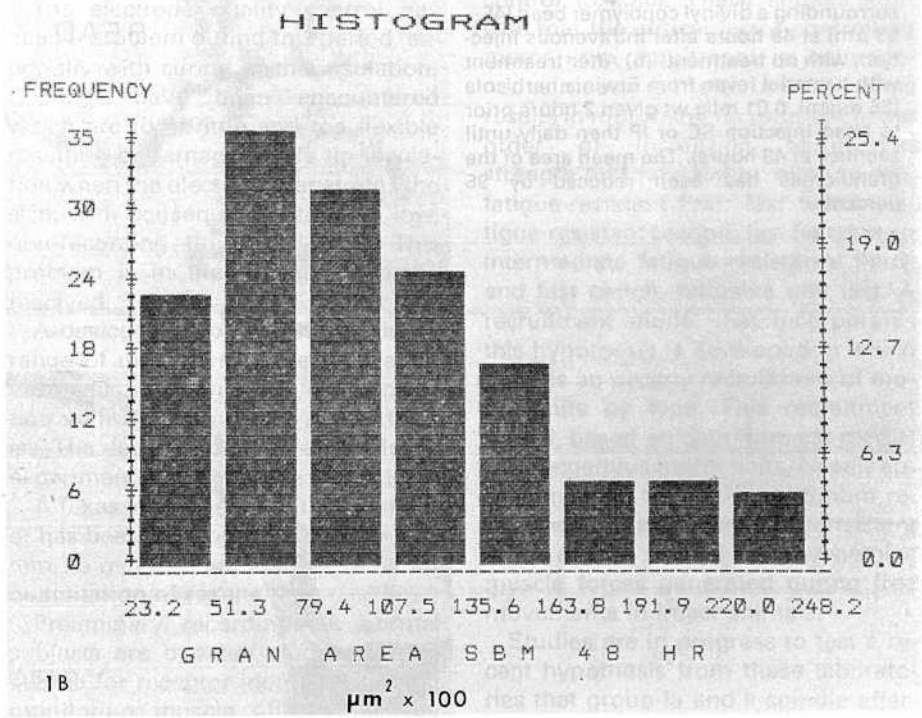


FIGURE 1.
Computer-derived histograms of granuloma areas surrounding 45–53μm divinyl copolymer beads. (a) Distribution of granuloma areas (μm²) at 3 hours after intravenous injection of beads. This is an early stage when only a few polymorphonuclear leukocytes can be observed adhering to the bead and granuloma area is minimal. Mean area = 604μm²; (b) Distribution of granuloma areas (μm² × 100) at 48 hours after intravenous injection of beads. The granuloma has reached a maximum size and is composed of both polymorphonuclear and mononuclear cells. Mean area = 10,090μm².

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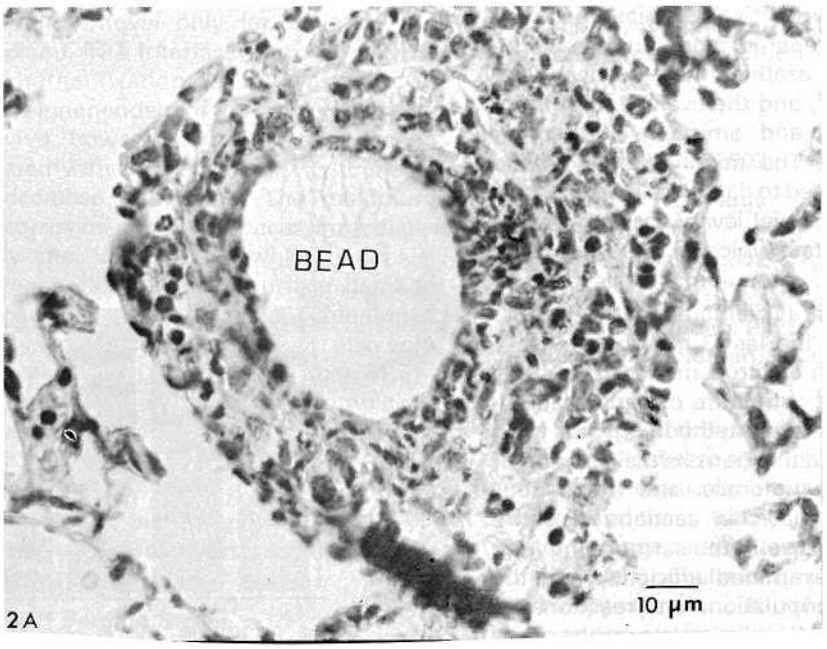

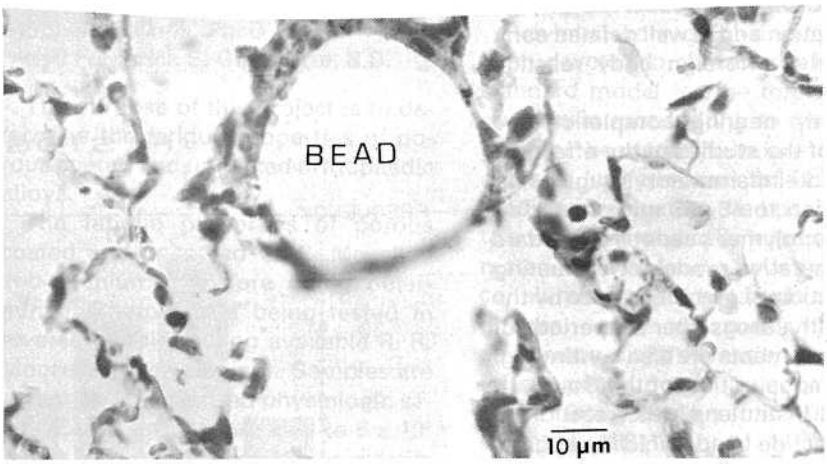

FIGURE 2.
The divinyl copolymer bead model provides a reproducible and quantitative method for measuring the effectiveness of anti-inflammatory drugs. (a) Granuloma surrounding a divinyl copolymer bead (45–53 μm) at 48 hours after intravenous injection, with no treatment; (b) After treatment with bacterial levan from Erwinia herbicola (25 mg/ml, 0.01 ml/g wt given 2 hours prior to bead injection SC or IP then daily until sacrifice at 48 hours). The mean area of the granulomas has been reduced by 95 percent.

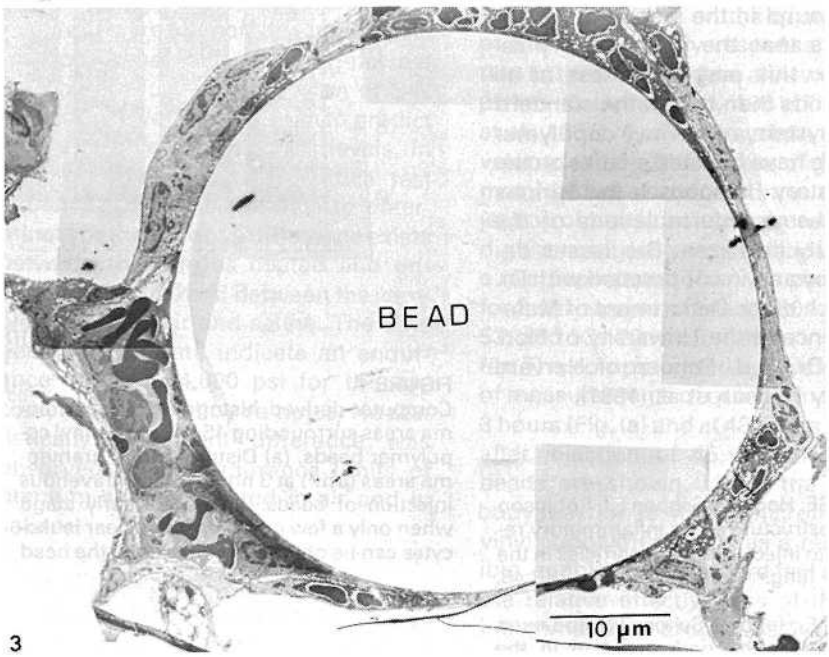

FIGURE 3.
Collage of electron micrographs showing the activity around a divinyl copolymer bead 12 hours after intravenous injection of beads. The micrograph illustrates the effectiveness of ultrastructural studies in elucidating the dynamic changes in cell populations during early granuloma formation.

Development of Upper-Extremity Orthoses Employing Electrical Stimulation

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The purpose of this project is to develop and evaluate an upper-extremity orthotic system, employing functional electrical stimulation of paralyzed muscle to provide control of grasp and release in the quadriplegic patient. Palmar prehension-release or lateral pinch-release is elicited by electrical excitation of forearm and hand muscles via percutaneous electrodes.

Seven outpatient and two inpatient subjects who have C5 or C6 levels of function are utilizing the FES device to achieve controlled grasp-release. We are continuing to monitor their ability to perform manipulation tasks, while at the same time developing the next generation of stimulator. The next generation stimulator is to provide control of two different grasps and provide flexibility in programming the control task. Presently, a hybrid stimulator system has been developed which utilizes a CMOS microprocessor (Motorola 6805) for performing command functions but continues to use the stimulator hardware from the previous generation stimulator. Development of the hardware of the system is complete, and one control task has been implemented. This control task allows us to use one control site, the shoulder, to generate both the proportional and logic signals. A laboratory version of the system has been utilized successfully by one subject.

In the next period, we plan to implement additional control software and to begin redesign of the hardware into a small patient portable device.

A Single Unit Study of Muscle Afferents in Human Movement

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The overall objective of the project is to study the role of the alpha motor-fusimotor systems in human normal and pathological movement. An electrophysiology laboratory has been established to monitor and record single unit afferent nerve potentials from muscle receptors in the awake, unanesthetized human. Potentials are recorded from the median nerve at the elbow and posterior tibial nerve in the popliteal space. Electrical stimulation through the recording electrode allows for muscle afferent nerve fascicle isolation for rapid muscle spindle nerve fiber identification. Electrodes are insulated tungsten wires, electrolytically tipped, fabricated by Frederick Haer Company, Brunswick, Maine.

The electrode quality control has been a problem during this period, especially with curing of the insulation. Coatings have been encountered which are too brittle and too flexible resulting in damage to the tip insulation when the electrode penetrates the skin, with consequent extremely low, non-recording tip impedances. This problem is in the process of being resolved.

A device to record wrist and finger range of movement is being custom designed and fabricated in cooperation with Bioengineering and Orthotics. The device should be available for experimental testing in the near future.

A Texas Instruments 990–5 computer has been incorporated into the system, to begin to initiate programs for quantitation of results.

Preliminary recordings in normal subjects are directed at determining criteria for receptor identification and monitoring muscle afferent activity during rest, passive stretch, muscle twitch, reflex and voluntary movement. Studying muscle afferent activity in patients with hyperactive syndromes and phasic movements (Parkinsonian and cerebral vascular accident patients) is projected for the future.

Segmental Motor Control

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This project was instituted to elucidate the principles of organization of motor control at the segmental or spinal-cord level.

Recent studies from these laboratories have demonstrated the functional monosynaptic organization of the mammalian muscle spindles (muscle stretch receptors) onto spinal alpha motoneurons (1,2).

Recent studies from these laboratories have major significance for hypotheses regarding segmental motor control (3,4,5,6). These studies indicate that the critical factor controlling motor unit recruitment in heterogeneous muscle is motor unit type. This results in motor unit recruitment in the order of increasing contraction strength and fatigability: slow twitch, fatigue-resistant first; fast twitch, fatigue-resistant second; fast twitch with intermediate fatigue resistance third; and fast twitch, fatigable unit last. A recruitment model that incorporates this hypothesis is developed in which there is an orderly recruitment of motor units by type. This recruitment model, based on data from cat medial gastrocnemius motor units, closely approximates a theoretical optimum recruitment strategy and is consistent with actual medial gastrocnemius muscle forces generated during free movements in intact animals.

Studies are in progress to test a recent hypothesis from these laboratories that group Ia and II spindle afferents may comprise a single continuous functional system that is organized in adherence to a size principle (2).

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Nerve Conduction Velocity Distributions: Clinical Research Applications

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The objective of this work is the development of sensitive, non-invasive, electrophysiologic techniques for the study of the dynamics of peripheral nerve growth, development, damage, disease, healing, and response to treatment.

Initial studies of the distribution of conduction velocities (DCV) have demonstrated that such DCV analysis provides a reliable measure of nerve-bundle conduction characteristics that can detect subtle peripheral nerve abnormality even when conventional electrophysiologic techniques yield normal findings (Cummins and Dorfman, 1981). Currently, we are comparing estimates of DCVs obtained using three different computer-based methods.

We have estimated the DCV of large myelinated fibers in the median nerves of normal subjects and patients with neuromuscular disease, using the following methods: (i) a deconvolution method based upon two surface-recorded mixed sensorimotor compound nerve action potentials (CAPs) separated by a known distance along the course of the nerve (2CAP method); (ii) a similar deconvolution method based upon surface-recorded compound muscle action potentials (MAPs) from the abductor pollicis brevis, in response to activation of the nerve trunk at two points separated by a known distance (2MAP method); and (iii) a collision neurographic technique based on two-point stimulation of the nerve and the resultant MAP (CMAP method, Leifer, et al., 1977). The 2CAP method gives information about both motor and sensory nerve fibers, whereas the 2MAP and CMAP methods test only the alpha motor fibers.

Representative parameters of the DCV in normal young adults had the following values (± standard deviation) for the three methods (2CAP/ 2MAP/ CMAP):

peak CV = 59.8±1.8 / 46.0±2.8 / 47.8±0.6;

mean CV = 57.4±2.9 / 45.6±2.9 / 46.6±1.9;

maximum CV (5%) = 68.8±2.9 / 50.8±3.9 / 50.9±2.2;

minimum CV (95%) = 42.5±5.0 / 38.8±3.4 / 38.8±3.2 (all in meters/ second).

Thus, the two motor techniques gave very similar quantitative results, whereas all corresponding values were higher for the 2CAP method ($p < 0.01$, 2-tailed); the difference presumably representing the properties of the faster-conducting sensory fiber population. By applying both the mixed-nerve DCV and one of the motor DCV estimation procedures, it is possible to derive discrete quantitative population indices for the large myelinated motor and sensory fibers in a human peripheral nerve trunk.

Progress has also been made toward development of a stand-alone system for estimating DCVs using the 2CAP method. We have succeeded in implementing the DCV algorithm on the Nicolet Instrument Corp. 1280 processor used in the Nicolet Pathfinder II system. We are currently working to integrate this algorithm into the clinical software package for the Pathfinder II.

We are continuing our study of diabetic patients in an effort to follow the course of diabetic neuropathy in response to dietary control and drug treatment. That study is principally an evaluation of the ability of our DCV methods to detect and follow the course of subtle peripheral neuropathy.

Also, patients with MS, hemiplegia, and spinal-cord injury are being studied in order to investigate the possible correlation of peripheral neuropathy with lesions of the central nervous system.

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Rehabilitative Engineering Support for the Atlanta VA Medical Center

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Gary W. Kelly

A Manual Wheelchair Wheel with Integral Anti-Rollback (Gary Kelly, Principal Investigator, and Roger N. Wahlberg.)

The purpose of this design is to enable wheelchair users to climb ramps and hills without rolling backwards when the pushrings are released and before the brakes are applied.

This prototype wheel can be substituted for existing wheels without modification to standard wheelchair frames. The wheel locks automatically into a forward-moving position and cannot roll backwards unless the user deliberately pulls back on the push rings. It is a spoke-less wheel requiring no maintenance.

Modification of the first prototype is largely complete. This design incorporates considerable user input and engineering experience gained from the previous design. The modification to the outer track bearing/clutch design provides for low power roll (an estimated reduction of 3 ± 1 lbs. dynamic pull) yet with increased features in handrail control including rollback lockout without sacrificing the low

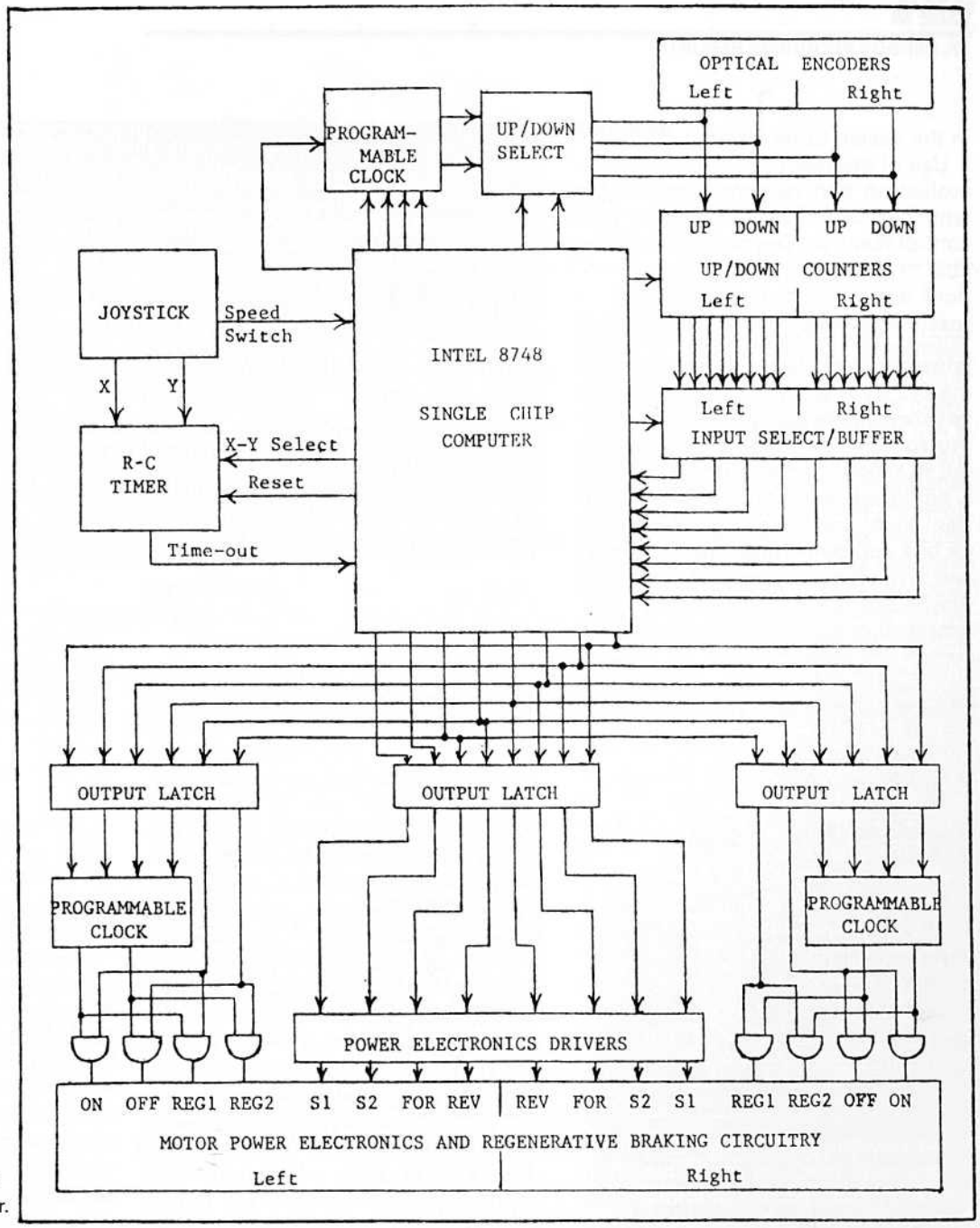

FIGURE 1.
Block diagram of proposed power wheelchair controller.

maintenance and rollback effectiveness. The chair wheelbase has been reduced by about 1 3/4 inches following the reduction of the width of the rim/wheel assembly and increased pinch protection due to totally internal roller clutch control. The handrail center pivot spider is eliminated with rail attachments exclusively to identical rollback clutch modules. Pivoting is provided by separate but integral lift-off cams with rack and pinion control utilizing bearing slip surfaces.

With the integral control and exclusive handrail hook-up, fewer misalignment problems should occur and module swap-out should be simplified. The weight of the overall assembly should drop by 10–15%.

Tests will be conducted with volunteers when this prototype is completed. The major question requiring an answer involves the relative advantage of anti-rollback vs. increased weight and increased rolling friction. Rolling friction is expected to be almost double that found in many standard wheelchairs.

An Alternate Vehicle for the Physically Handicapped. (Gary W. Kelly, Principal Investigator, and David A. Ross)

The purpose of this phase of the research is to develop an improved joystick control system (more precise user control and more energy efficient) for the proposed alternate transit vehicle described in previous reports. It also is being developed with the needs of current power chair users in mind, so that their vehicles could be updated by replacing only the control box and the electronics leading to the motors.

The previous designs were conceptual in nature and concentrated on mechanical aspects of the proposed vehicle. The present effort concentrates on control problems and their solutions.

A block diagram of the improved controller is shown in Figure 1.

The controller is built around a single-chip microcomputer (Intel 8748), a flexible semiconductor device which contains 1028 words of erasable, programmable memory. This program memory can be changed as required allowing changes and improvements

in the design to be tested.

Use of the microcomputer provides evaluation and response capabilities which in turn allow many safety and control features. The controller will be able to monitor actual chair speed and hold acceleration or deceleration to reasonable rates regardless of joystick position. It can also be set to ignore rapid changes in joystick position which may be caused by spasms, and it will maintain forward motion when the joystick is in a forward position regardless of surface conditions, and drive the chair at direction and speed indicated by the average position and direction of the joystick. (The design proposed here interprets all positions of the joystick as requested speeds, not as accelerations.)

In the current design, the controller would interpret positions of the joystick as graphed in Figure 2, where the horizontal axis represents the amount of rotation of the joystick to the right or left or straight ahead. If the joystick were pushed forward to call for a forward speed of 1 mile an hour and then rotated left or right by a specific number of degrees, then the speed at which each wheel would turn can be read (in mph equivalents from the graph's central vertical axis scale) at the level where the vertical from that point on the joystick degree scale intersects each wheel's curve.

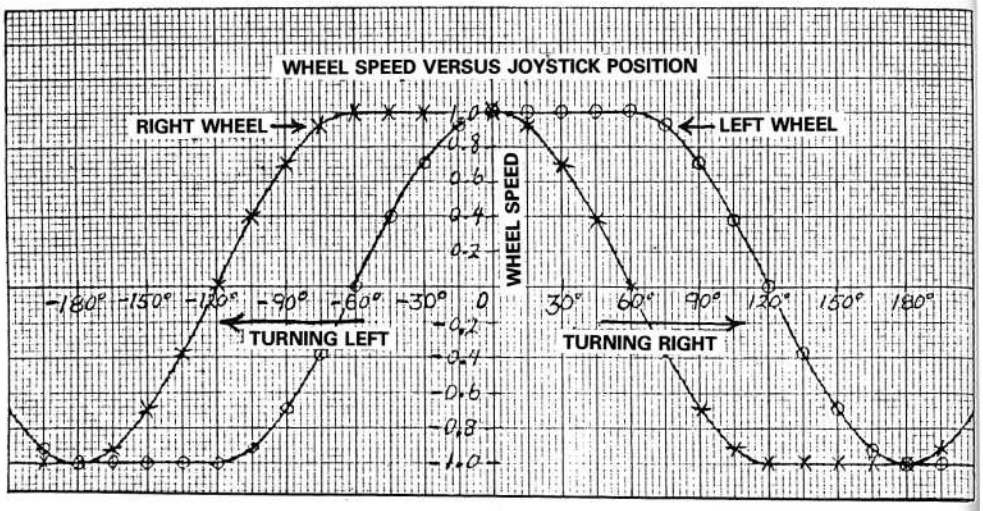

FIGURE 2.
Left and right wheel speeds versus angle of rotation of the joystick, in a proposed microcomputer controlled wheelchair controller.

Note that the user can sweep through 120 degrees (from 60 degrees left to 60 degrees right) without causing either wheel to reverse. At exactly 60 degrees, one wheel is about to stop while the other maintains its forward speed: at more extreme joystick angles one wheel begins to reverse while the other starts to reduce its speed of rotation. With the joystick rotated 90 degrees from forward position, the wheels would be turning in opposite rotations and the chair will be turning around in place.

The 120 degrees of latitude sweep without producing wheel reversal is an increase over the 90 degrees of standard steering, and will allow more control with fewer corrections.

Note also that straight-ahead motion is a stable condition in the control system expressed in Figure 2.

The proposed controller circuit should never need to be balanced for equal left and right wheel motion because the microcomputer is employed to check and regulate the speed of both wheels automatically. To make this possible, an inexpensive optical encoder is used on each driveshaft: pulses from these are compared to the programmable clock pulse connected to the same counters, and power sent to each wheel is adjusted to match the joystick performance commands and standards.

The proposed controller is expected to be very energy-efficient. It will use an energy-recovering "chopper" driver circuit, and a regenerative braking system to pulse power back into the battery. The chopper circuit will be tuned to operate at about 10 kilohertz which should help reduce inductive energy losses, keep down cost and size of inductors and capacitors, and make the controller operate very quietly.

The motor circuit is shown in Figure 3. Q1 and Q2 are the main silicon-controlled rectifiers (SCR's) which drive the motors. Q3, Q4, and Q5, together with capacitors C1 and C2, turn off Q1 and Q2 when triggered approximately. Cyclic recovery of energy remaining in the inductors and motor each time that

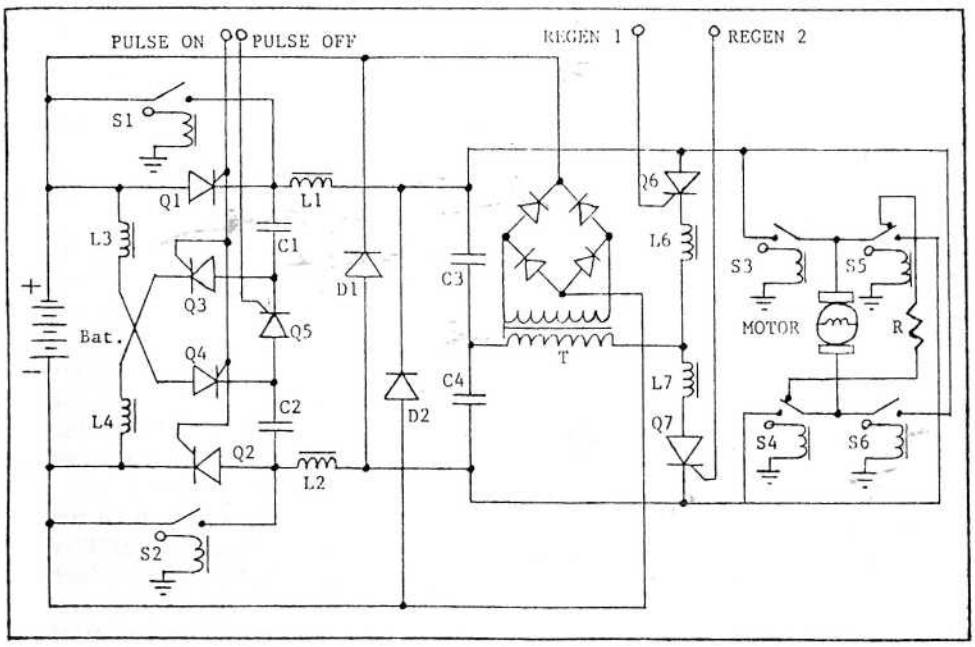

FIGURE 3.
Motor control power electronics and regenerative braking circuit.

Q1 and Q2 are turned off is recovered through the use and placement of diodes D1 and D2. These freewheeling diodes are connected in such a way that the motor's current will be directed back through the batteries each time Q1 and Q2 shut. To the right of the diodes is indicated the regeneration circuitry controlled by the SCR's Q6 and Q7. This type of regeneration has always been possible with the permanent-magnet motors used on wheelchairs, but without a microcomputer regeneration is very hard to control precisely and could damage the motors or the batteries, or cause sufficient deceleration to throw the person from the chair.

With the microcomputer chip, the regenerative system is capable of bringing the chair to nearly a complete stop on hills while recharging the batteries, and then to a complete stop using a low resistance motor shunt. Then, if the hill is very steep, the 8748 would have to apply reverse power to hold the chair in place. At that point a warning buzzer would sound indicating that the battery was being drained rapidly and that the user should lock the brakes if he wishes to remain stationary for more than half a minute.

At present, none of the above has been implemented in hardware, nor physically tested on a power chair. A "real time" computer simulation of this system is currently being implemented and will be tested with the aid of present power chair users. When this additional computer data and user data are obtained, the system will be redesigned as necessary and then implemented on an actual chair for further testing.

Additional projects of this group will be found under the "Sensory Aids" progress report heading, which follows.

SENSORY AIDS IN THE VA RER&D SERVICE PROGRAMS

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Sonic Orientation and Navigational Aid (SONA) (Gary W. Kelly, Principal Investigator and Theresa Ackerman, Research Technologist.)

The Sonic Orientation and Navigational Aid for the Visually Impaired Traveler is designed to provide auditory cues to the environment by means of a remote-control unit carried by the user. It has the additional function of a decentralized environmental control for manually impaired users.

By modifying the technology existing in remote control garage door openers, several prototypes of a hand-held digital code transmitter and numerous tone-generating receivers have been constructed.

The design and principle of operation remain the same, but the transmitter has undergone production design and will now accommodate over 350,000 possible codes. Each discrete digital code can be utilized to activate a different receiver. This design required modification of the new model transmitters and receivers. The latest prototypes have printed circuit boards that plug together to accommodate the touchtone keypad input. The unit size is similar to the size of a hand-held calculator, varying mostly in thickness. The limiting factors on size reduction have been the dimensions of the keypad and the size of the nine-volt transistor battery. Users who have been exposed to the device prefer its present size since it is "comfortable" to hold and the keypad is easy to use.

The new designs of the system are intended to facilitate the use of this device by quadriplegics, and to provide a decentralized environmental control system. The first such system is now being constructed and installed in a veteran's home and will permit him to control a large number of devices in his environment including a security system, electronic door lock, lights, stereo, microcomputer, and an automatic leg bag evacuator. The system is claimed to have many advantages over the BSR-based systems, due to its large number of unique codes.

The system is now being produced in sufficient numbers for initial field testing over the next year.

Efforts will continue to lower the costs of these units, which are now actually acceptable at $55 per transmitter and $35 per receiver. The receiver costs are much lower for the switching units as opposed to the sound-generating units used for the visually impaired traveler. It is expected that initial work will begin on a multiple-code receiver for elevator use, and initial tests of speech output response for the receivers.

Electronic Typewriter for the Visually Impaired (Gary W. Kelly, Principal Investigator and Theresa Ackerman, Research Technologist.)

The electronic typewriter with its integral tape recording capabilities allows users with low vision to record, on the same cassette, voice via microphone or material in binary form through keyboard entries. The latter is presented on a large print electronic display screen which is easily accessed using taped voice cues.

Special attention has been given to the electronic display to insure maximum legibility for those with partial vision. Each character is two-tenths of an inch high and can be presented in different colors at a user-controlled rate of speed.

This project has been accelerated 2 years ahead in the past 6 months, thanks to the advent of the Sony Type-

corder. The Typecorder is a battery-powered wordprocessor with full typewriter keyboard and a size comparable to a cassette recorder. It stores information in a microcassette and comes complete with a 40-character liquid crystal display. Previous reports describe the development and capabilities of the electronic typewriter which is, in many respects, similar to the Sony Typecorder.

With the purchase of a Sony Typecorder, new efforts have begun, with the cooperation of Sony, to create a hybrid device utilizing the Georgia Tech display interfaces and Sony's basic device. Sony Corp. utilizes the same RCA 1802 microprocessor as the initial Georgia Tech prototype, and a 40-character display. The interface and modifications are going well as a result. It will interface with a 40-character vacuum fluorescent display and standard CCTV monitors. Although the adaptation to the Sony device will sacrifice some capabilities of the initial design, this drawback is more than offset by the relatively short time in which this device may become available nationally, with servicing, and at a reasonable cost.

Estimated completion time for the new prototype is 6 months.

A Musical Language Computer Terminal for the Visually Impaired (Gary W. Kelly, Principal Researcher, and David Ross, Graduate Research Assistant.)

The Musical Language was developed on an Apple II Computer to provide blind computer operators an alternative computer terminal which could enable them to enter and edit data and text quickly and efficiently.

The Musical Language which maximizes the probability that tone combinations are musically pleasing, and in which the sound of a word is synonymous with the spelling of that word, has been designed and implemented on a computer terminal assembled from existing hardware.

The most recent improvements in this system have been in the area of software developments and originated both on the market and in the lab. The tone-generating software for the ALF Products' Music Board has been improved to allow use of the nine-voice board, which lacks some features of the three-voice board but is still suitable at a significantly reduced cost.

Within the project, major attention has been given to the development of training software to teach the musical language to blind persons. This training system uses the Apple II as a self-contained training machine. With the addition of the Votrax Speech Synthesizer, this program can verbally explain itself to the listener and can then begin to present simple vocabulary words in both verbal and musical form. After this only the musical form is presented and the learner indicates recognition of the word by typing it on the keyboard. After a correct response (or five incorrect responses) the computer will pronounce the word and proceed to the next one. As the vocabulary and the correct scores increase, the machine will begin to present word combinations and finally sentences. The present vocabulary consists of 60 common words, but the user may also type in his own vocabulary which will be turned into a lesson and presented on request.

The system is set up to be user-friendly, allowing the visually impaired learner to use the program without outside help.

Typing ability is a definite advantage in using this system, and software is planned which will train the learner to type, a very useful skill in itself. Also, there are plans to develop additional software so that the Musical Language can be utilized with a text editor package available for the Apple II plus.

Communicator for the Speech Impaired (Gary W. Kelly, Principal Investigator, David A. Ross, and Theresa Ackerman.)

The Electronic Communicator for speech impaired persons is designed to allow them to communicate quickly whether composing a new message or activating a programmed one.

The past 6 months have seen the construction of two new models of the communicator. One has 112 lines of user-programmable messages which may be linked in any length desired, including all 112 lines. Each line is 16 characters long which is the length of the LCD display. Any message may be edited or changed independently of any other line of message, and if a message is already stored in a given location it will be displayed to determine if the user wishes to write over it. The communicator can be used for spontaneous speech or in combination with stored messages.

Two units have been constructed. One has a 16-button keypad and the other offers a Morse code joystick system for those users who are manually impaired as well as speech impaired. The major differences between the two are the interface with the input mode, and the casing; the software is the same. One routine translates Morse code into alphanumerics, and the other is a more direct conversion from the 16-button matrix to alphanumerics.

This project is now at an early conclusion, due to cut-backs in funding. If alternate funding can be obtained, future models will feature both joystick and keypad input. Recent advances in integrated circuitry could also lead to a less-complex power supply and reduced battery size, because newer versions of the eeproms require only 5 volts to erase them as opposed to 21 volts. This should allow the overall size, weight, and general design to be improved.

Development of a Camera for Application in Sensory Aids for the Blind

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The purpose of this project is to develop a new camera for the speech-output reading machine to be made by Telesensory Systems Inc. This reading machine for the blind will allow the user close control of the text being read, by using manual scanning of the text with a hand-held camera. As with the Optacon, the hand-scanning will be guided by tactile feedback. The new camera will generate higher quality images of ink print appropriate for machine reading. In addition, the new camera will have a wider field of view than the Optacon camera, so that the user will be allowed a reasonable tolerance for error in tracking the lines of text without degrading the output. The tactile output available from the Optacon will also be available from the new

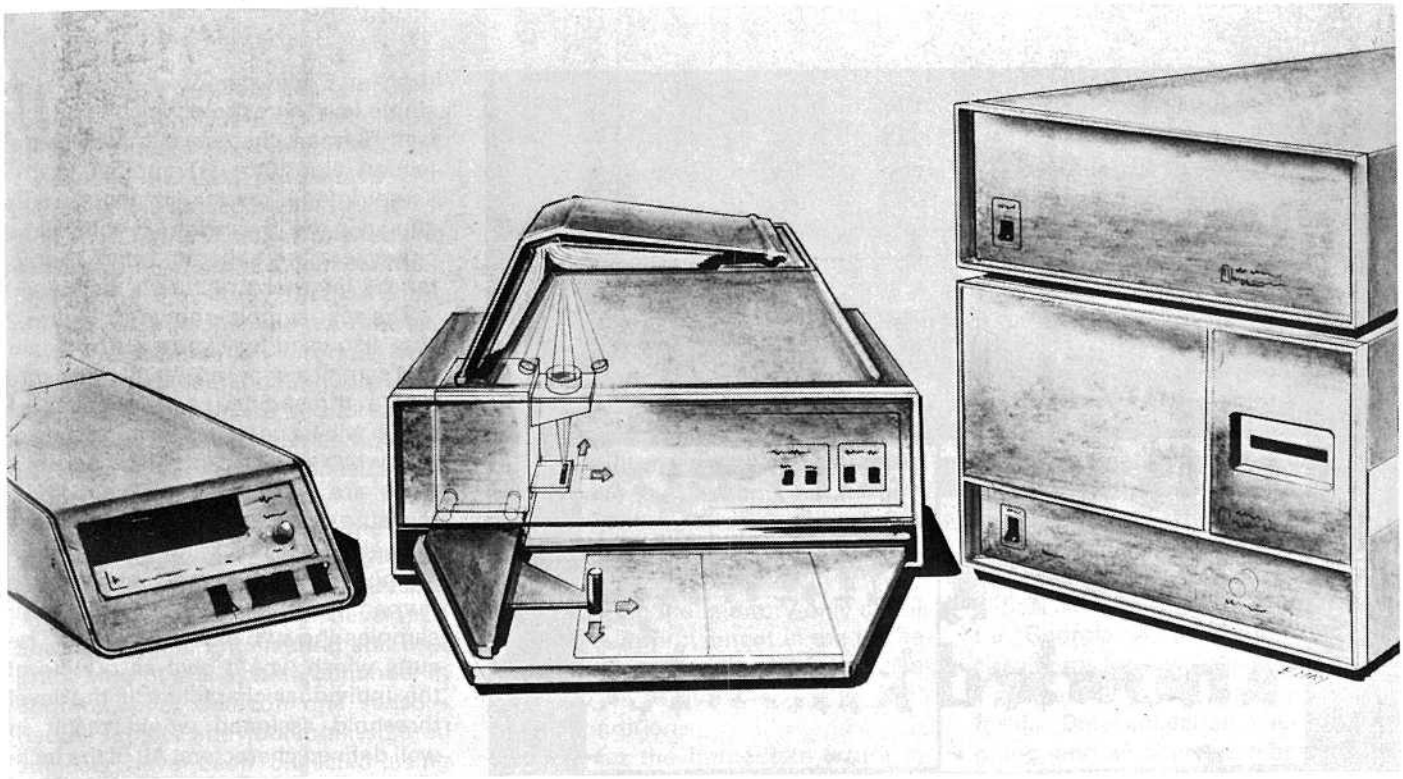

FIGURE 1
The new combination camera and tracking aid is shown in the center; the standard Optacon is on the left and the electronics package for the prototype reading machine is shown on the right.

camera system. The design goals for the new camera system and the corresponding analysis which leads to these goals can be found in the two previous issues of the Bulletin of Prosthetics Research.

Although thresholding studies began at the RER&D center in FY 81, TSI began the major development work on this project under contract on October 1, 1981. Based on early results of the prototype reading machine evaluation under a separate contract, the originally proposed design of the camera system has been improved. The results showed that the major difficulty in obtaining good output from the prototype reading machine was the problem of tracking the lines of text well enough for good machine acquisition and recognition of the characters. In addition, interviews with evaluators and users of the prototype systems suggested that, while the original plans for a new camera called for a larger field of view (for easier hand tracking) and higher resolution and speed in a camera that was easily held in one hand, a better design might include a built-in tracking aid. This would both increase the usefulness of the new camera and simplify the design because the new optics, illumination source, and electronics could be incorporated in the tracking aid rather than in the hand-held part of the camera. A preliminary design of such a camera was developed by TSI and is shown in Figure 1. (In Figure 1, the combination camera and tracking aid, which can be used on a desk top, is shown in the center. The standard Optacon is seen on the left, and the electronics for the prototype speech-output reading machine is shown on the right. In the center drawing of the camera/tracking aid, the three levels of the device can be seen. On the projecting tray-like surface at the bottom, the user moves the small vertical pointer as if tracking lines across a page beneath it. In so doing, the user is actually manipulating the optical system seen on the middle level: the optics are focused upwards on the book page which is tightly held face-down across the top opening of the camera/tracking-aid combination.)

At the RER&D center, work continues on the development and analysis of thresholding strategies, magnification determination, and algorithms for detection of text vs. picture. This research is done with $512 \times 512 \times 8$ images of text digitized at various magnifications and angles of skew. Results to date indicate that the resolution requirements of the new camera can be relaxed by 10% to 20% if thresholding techniques more sophisticated than simple level thresholding are used (1).

Figure 2 shows a sample of 6 pt text digitized so that the height of the small letters is 9 picture elements (pixels) high. For good images of characters using level thresholding, a height of 12 pixels is required (1). The sample in the upper left of this picture is digitized at 6 bits per pixel, since limits of dynamic range prevented full utilization of the eight bits available. The upper right shows the same sample truncated to 5 bits per pixel. The lower left shows a choice of threshold value for level thresholding which preserves most of the character image at the cost of joining some letters and losing internal character structure. If the level were lowered to capture all of the "s" in "was", the image would not be readable. Raising the threshold does not substantially increase the resolution within characters, and does lose important structural components of the characters. Thus, for this image digi-

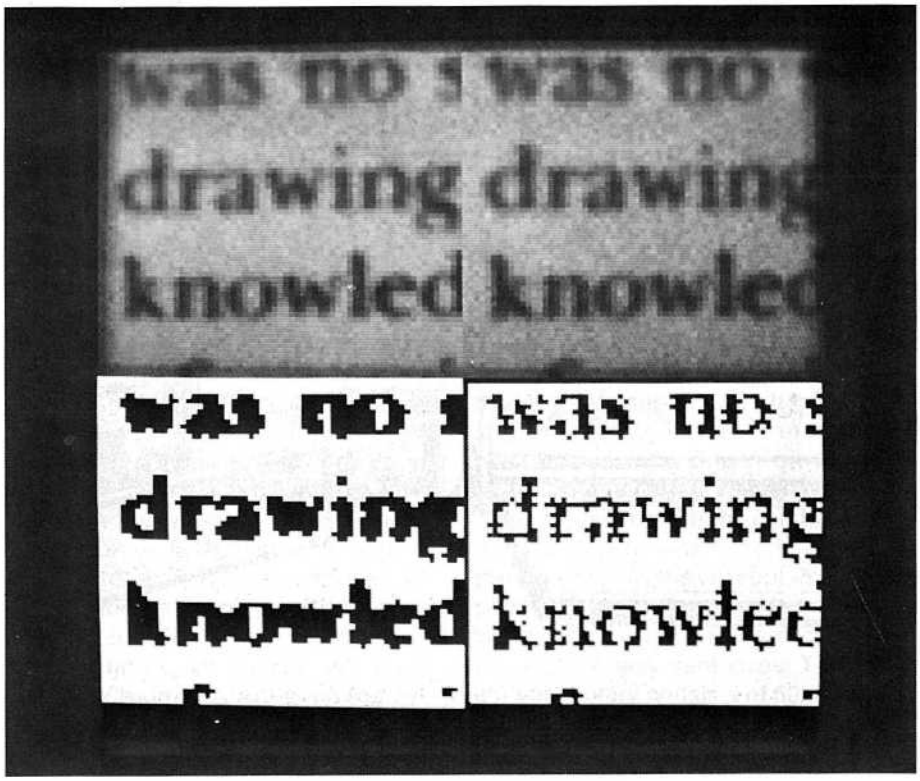

FIGURE 2
The upper left shows a 64×64×6 selection of digitized text. The upper right shows the same selection digitized to only 5 bits per pixel. The advantages and disadvantages of level thresholding and edge detection are compared in the lower samples.

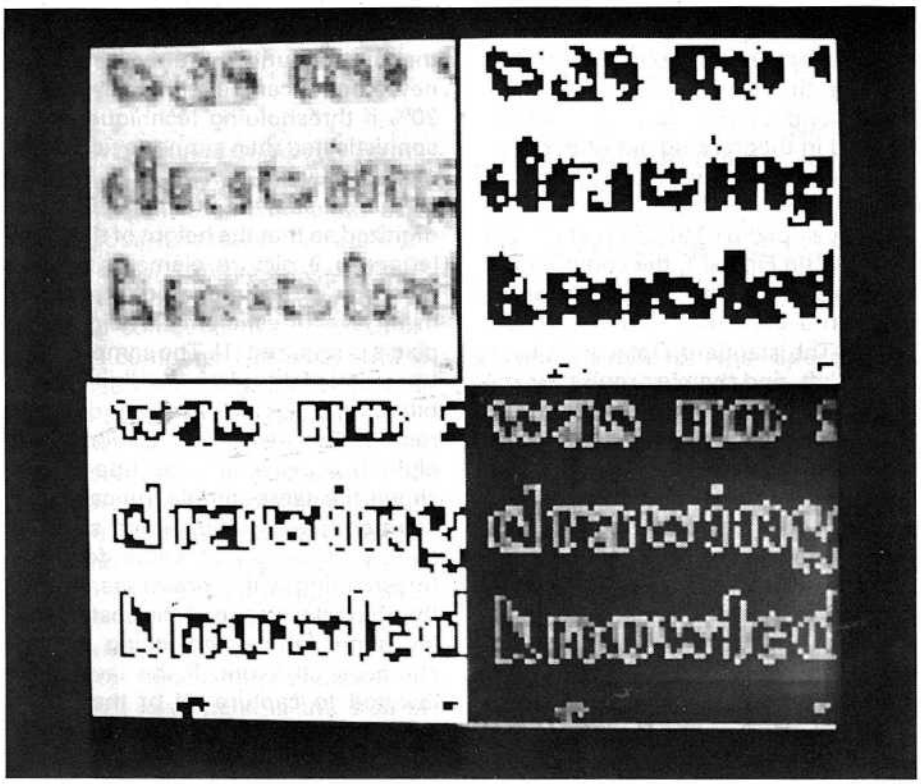

FIGURE 3
The upper samples show an "activity measure" which can distinguish text from pictures. The lower samples show banded thresholding results which may be useful in thresholding and in picture vs. text detection.

tized at 6 bits per pixel, there is **no single level threshold** which results in well defined characters. An edge-detection algorithm (1) applied to the same image results in the sample shown in the lower right. In this image characters are separated and characteristic internal structure is visible.

The text sample shown in Figure 2 was also used for Figure 3. The upper two samples show an activity measure and a thresholded activity measure which will be useful in isolating area of text when non-text graphics and pictures are also present. The activity measure used calculates the difference between each pixel and its surrounding pixels. This is somewhat similar to human visual processing. The lower samples show "band thresholding" results which would give an outline of the individual characters if the level threshold assigned would result in well defined characters. All of the techniques shown in Figures 2 and 3 can be used together to acquire good images of text from uncontrolled input.

The results of magnification and threshold studies will be used to decide whether digital or analog techniques will be used in the image-processing section of the new camera. At TSI, the construction of the optics and electronics for the first camera, as shown in Figure 1, will continue.

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A Tactile Aid for the Treatment of Sensorineural Hearing Loss and Aphasia

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This is a clinical trials study to test the efficacy of Teletactor (a wearable electrotactile sensory aid that converts auditory stimuli to tactile impulses displayed through a belt on the abdomen) as a treatment for speech discrimina-

tion deficit in severe sensorineural hearing loss and for auditory comprehension deficit in severe aphasia.

Previous investigations have employed tactile aids to present visual information to the visually impaired and acoustic information to deaf children. This is the first study that tests the efficacy of a tactile aid to improve speech discrimination in adults with severe sensorineural hearing loss and adults suffering severe auditory comprehension deficit as one component of Global or Wernicke's aphasia.

During the period July 1, 1981 through December 31, 1981, the computer system to generate and present acoustic and tactile stimuli and record subject responses has been developed and assembled. Engineering and programming of this system continue. In addition, pilot data on one sensorineural subject and four brain-injured subjects have been collected using "live voice" stimuli and manual presentation. An additional brain-injured subject is currently active in the study.

The data to date yield more information about the experimental design, the treatment tasks, and the inadequacy of testing the efficacy of Teletactor with "live voice" stimuli than they do about the efficacy of the device as a treatment aid. Generally, the sensorineural subject improved his discrimination of monosyllabic words during the treatment period when he was wearing Teletactor. Discrimination when wearing Teletactor improved 28% compared with a 16% improvement when it was not being worn. During the second 8 weeks of the treatment trial, when he was treated without Teletactor, discrimination when wearing Teletactor declined 4% compared with a 16% improvement when not wearing Teletactor. Our experience with this subject indicated a necessity to eliminate visual (speech reading) cues if we are to test the efficacy of tactile sensory substitution. Hard-of-hearing patients have a history of focusing on visual cues and may continue to do so during a treatment trial designed to focus attention on tactile information.

All of the brain-injured subjects improved on the treatment tasks: this improvement occurred during treatment periods with Teletactor and treatment periods without it. In only one of the four subjects, the most severe, improvement on treatment tasks generalized to the more general language tests used as criterion measures. One brain-injured subject was run in an experimental design of random assignment of treatment methods to sessions (with Teletactor vs. without Teletactor) rather than our proposed time-series design (8 weeks wearing Teletactor vs. 8 weeks not wearing it). This permitted baseline, treatment, and posttreatment comparison in three conditions — auditory stimulation, tactile stimulation, and auditory and tactile stimulation combined. Pre- and post-treatment comparison in the three conditions indicated a 17% improvement in the auditory-only condition, a 2% improvement in the tactile-only condition, and a 16% improvement in the auditory and tactile combined condition.

Plans for the immediate future include activation of the computer system to deliver auditory and tactile stimuli, and replacement of the time-series design with the random assignment of treatment methods to sessions design.

The computer system is in the final stages of development. It will be completed by April 1982. The random assignment of treatment methods to sessions design will permit a more direct test of the efficacy of Teletactor and shorten the duration of the proposed treatment period. Two subjects with severe sensorineural hearing loss and three brain-injured subjects have been screened. All meet selection criteria and will begin the treatment trial in April 1982.

Design Evaluation of the Hand-Scan Voice Output Reading System

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The purpose of this project is to provide design feedback on the field test units of the TSI Hand-Scan Voice Output Reading System through its use and evaluation by blind individuals for educational, vocational, and personal reading. (Under interagency support from the Veterans Administration, Rehabilitation Services Administration, and the (then) Bureau of Education for the Handicapped, Telesensory Systems conducted a major portion of the research leading to the development of the field test units presently under evaluation.)

At the writing of this report, 9 of the 12 project months have elapsed. A training session was held for evaluation site coordinators, and followng their training, the field test units were placed with them in locations around the country. Stationary evaluation sites are the VA's Blind Rehabilitation Centers in Palo Alto, Calif. and Hines, Illinois and in a school system in Decatur, Georgia. A fourth unit has been circulating for 6-week periods in individual employment trials within California. Data collection has been ongoing, and all sites have been visited and monitored by the principal investigator. There have been only two critical incidents involving these four units. One updated software program has been issued.

Data collection will continue at the three stationary sites through the month of April. During May, collected data will be analyzed and results compiled. The unit circulating in individual employment trials will be used in one final site, where data can be gathered about its use for technical reading by a blind rehabilitation engineer. Following the evaluation period, considerations for product feasibility and design modification will be undertaken.

An Auditory Prosthesis for Sensorineural Hearing Loss

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The purpose of this study is to use a theoretical model of pitch processing to determine the suprathreshold characteristics of an individual's hearing loss. The results obtained will be used to design a compensatory signal-distorting hearing aid intended to cancel out the perceptual effects of the hear-

ing loss. Previous studies have indicated that the model is able to characterize performance differences among subjects with normal hearing. Measurements of suprathreshold auditory function in the first group of six subjects with cochlear pathology is nearing completion. Both pitch and loudness functions are being studied at the standard audiometric testing frequencies from 250 through 4000 Hz.

Three aspects of the results can be mentioned briefly:

1. Hearing impaired subjects often, but not always, have frequency discrimination deficits at frequencies where there are elevated thresholds;

2. Such subjects also show abnormal intensity-response (I-R) functions as measured by the dichotic pitch paradigm described in detail in our RER&D Research Proposal. While the I-R function abnormalities tend to occur at the same frequencies as the threshold elevations, neither the presence nor the degree of the threshold elevation indicates the extent or the nature of the I-R function abnormality; and

3. Some of the hearing impaired subjects have demonstrated considerable binaural diplacusis that has no obvious relation to the extent of the threshold elevation.

Future plans (as described in our proposal) include using the I-R function and other results to design and test a compensatory signal-distorting hearing aid for each subject. The aid will exist as a computer program with the individually preprocessed signal being delivered to the subject through a two-channel ("binaural") D-to-A converter. At the present time, further computer hardware and software development is essential to carrying out these later studies. In the immediate future the laboratory will have the capacity to study more subjects simultaneously and thus to double or triple the number of subjects tested concurrently.

The Clinical and Acoustic Parameters of Hearing Aid Effectiveness

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Recent work has been directed toward determination of performance-intensity functions, interlist equivalency, and test-retest reliability of the 10 lists of the recording of the Maryland CNC (consonant-vowel nucleus-consonant) Test (Male Speaker) for groups of subjects with normal hearing and sensorineural hearing loss.

Recording and analysis of the CNC materials is part of an ongoing project to develop sensitive test materials for hearing aid evaluation purposes. A summary of previous work in this area appears in the Fall, 1981, issue (Causey et al., 1981). In that report, it was shown that the Maryland NU 6 and Maryland CNC Test materials generally made similar distinctions in word recognition ability among hearing loss configurations. Further analysis has been necessary to determine similarities between the tests in a more detailed manner and to evaluate the suitability of the CNC Test for clinical use.

Performance-intensity functions have been derived for 60 normal-hearing subjects (mean age 21 years, range 18–26 years) and 40 veterans with mild to moderate sloping sensorineural hearing loss (mean age 54 years, range 30–74 years). Test stimuli were presented to normal-hearing subjects at sensation levels (SL) of 4 to 40 dB re SRT and to hearing-impaired subjects at 12 to 48 dB SL. Results shown in Table 1 indicate a function with a 4.8% per decibel rise from 4 to 16 dB SL and an asymptote of 95% at 40 dB SL for normal-hearing subjects. For this group, all 10 lists were used and were found to be equivalents. Overall placement and configuration of the function is quite similar to the Maryland NU 6 function for normal-hearing subjects (Causey et al., 1981) although mean scores at the highest presentation levels were higher for the NU 6 than the CNC Test. For hearing-impaired subjects, the performance-intensity function is much flatter (1.4% per decibel rise between 12 and 28 dB SL) with a plateau of 70% at 44 dB sensation level. For this group, five lists determined to be equivalent with hearing-impaired listeners were used. Performance of hearing-impaired subjects is better on the Maryland CNC Test than the Maryland NU 6 Test, particularly at lower sensation levels. At the higher sensation levels (36 to 44 dB), the P-I func-

TABLE 1
Word recognition scores on the Maryland CNC Test as a function of presentation level.

Presentation Level (dB SL re SRT)	Word Recognition on Scores (%)			
	Normal-hearing group (n = 60)		Hearing-impaired group (n = 40)	
	Mean	(s.d.)	Mean	(s.d.)
4	13.97	(11.18)		
8	34.13	(14.28)		
12	55.83	(14.14)	40.90	(20.16)
16	71.57	(10.77)	46.10	(19.76)
20	78.00	(10.10)	51.80	(22.78)
24	85.53	(6.95)	56.30	(18.15)
28	90.10	(5.37)	63.60	(23.70)
32	92.47	(3.71)	62.70	(19.97)
36	93.33	(3.58)	65.30	(21.74)
40	94.90	(3.22)	65.20	(17.78)
44			69.70	(17.01)
48			67.30	(18.61)

TABLE 2
Rank order (easiest to most difficult) of Maryland CNC Lists 1-1 to 1-10, obtained on 20 sensorineural-hearing-loss subjects at 40 and 44 dB sensation level.

List	Percent Word Recognition	
	Mean	s.d.
1-6	75.70	16.25
1-9	75.10	14.10
1-1	73.30	15.45
1-10	71.70	16.38
1-7	71.10	16.65
1-3	70.90	13.62
1-4	68.50	16.23
1-2	66.40	17.37
1-5	65.20	17.86
1-8	63.30	16.57

tions for these two tests begin to approximate one another. Data presented in Table 1 allow comparison of performance between normal-hearing and hearing-impaired subjects on the CNC Test materials.

Equivalency among lists for hearing-impaired listeners was determined by presentation of all 10 lists at constant sensation levels to another group of listeners with sensorineural hearing loss. Ten subjects were tested at 40 dB SL and 10 at 44 dB SL. Since results at each level were similar, scores for the 20 subjects were pooled for analysis. Arc-sine transformed scores subjected to a repeated measures analysis of variance indicated significant differences among lists [$F(19, 171) = 9.3347$, $p < .001$]. Rank ordering of lists according to difficulty is shown in Table 2, along with the word-recognition score means and standard deviations. Post hoc comparisons (Tukey procedure, Winer, 1971) among lists indicated that Lists 1-6 and 1-9 were significantly different ($p < .05$) from the other eight lists, or, if determined in the other direction, List 1-8 was significantly different than the other nine lists. This means that either eight or nine lists can be considered statistically equivalent, depending on whether the one hardest or two easiest lists are eliminated.

Test-retest reliability data have been obtained for nine hearing-impaired subjects thus far. Results show correlations ranging from .82 to .97 with eight of the 10 lists showing correlations which were significant at $p < .001$.

Data collection is continuing with hearing-impaired subjects to clarify the equivalency and reliability of the Maryland CNC Test materials. The efficacy of this test and the Maryland NU 6 Test with hearing aids remains to be conducted, although preliminary work has produced encouraging results (Causey & Bender, 1980).

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Investigations of Acoustic Reflex in Elderly Persons

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This study seeks to provide quantitative information on the effect of aging on the human acoustic reflex. Data are gathered with an aural acoustic-immittance instrument.*

Tasks accomplished during the reporting period include interfacing of analog instrumentation with computer hardware, completion of initial stages of a software project on acquisition and measurement of acoustic reflex measures, and location of suitable research subjects in the 50-to-80-year age range.

An investigation has been completed on the validity of a technique used in measurement of the contralateral acoustic reflex (Thompson, Robinette, and Dunlop, 1980). The technique consists of presentation of a signal to one ear as an acoustic-immittance instrument monitors aural acoustic immittance in the other (contralateral) ear canal with a low-frequency probe tone. The use of both ears simultaneously is possible becasue presentation of a sufficiently intense sound to one ear results in contraction of the stapedius muscles ("acoustic reflex") in both middle ears. Contraction of the stapedius muscle is detected by the acoustic immittance instrument as a change in acoustic immittance at the tympanic membrane.

Broad-band noise was chosen as the test signal because of its clinical importance in prediction of hearing loss from acoustic-reflex thresholds (review in Popelka, 1981). Electrical spectra, recorded from acoustic-immittance instruments with a computing spectrum analyzer, were examined to determine whether the signal (transmitted across the head) was detected by the immittance instrument. Three commercial acoustic-immittance instruments were tested.

Results for one acoustic-immittance

*Refers to acoustic impedance or acoustic admittance measured in the ear canal (ANSI committee on development of a standard for aural acoustic-immittance instruments, Draft 1980A).

instrument indicated that the broadband noise, presented to the "signal" ear, reached the (contralateral) "probe" ear and was detected by the instrument. This transmitted signal distorted the acoustic-reflex responses of a normal-hearing subject and, in a subject without an acoustic-reflex response, produced deflections on the acoustic-immittance meter that were similar to acoustic-reflex responses. Clinicians were advised to exercise caution in interpretation of contralateral reflex responses to signals with energy near probe-tone frequency, until manufacturers provide information on this aspect of acoustic-immittance instruments.

Other work in progress includes development of software for a new acoustic-immittance instrument controlled by microprocessor, and a study of perstimulatory adaptation of acoustic reflex.

References

Popelka GR: **In**: Hearing Assessment with the Acoustic Reflex (GR Popelka, ed.) pp. 23–46, Grune & Stratton, 1981.

Thompson DJ, Robinette LN & Dunlop RJ: Transcranial Attenuation for Reflex-Eliciting Signals. Presented at the Convention of the American Speech-Language-Hearing Association, November 1980.

Development of a New Communication Control Aid Using Electromagnetic Tracking Technology

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A new direct-solution approach is being explored by designing and building a research-grade unit for clinical testing.

The project began on July 1, 1981, and most of the effort in the first 6 months centered on designing and testing the research instrument. No technical problems have been experienced to date. We are proceeding on schedule and the unit should be available for demonstration on or about June 15, 1982. A proposal for Phase II of the program (clinical evaluation at Trace R&D Center) has been submitted.

We plan to complete the present effort on time and within the budgeted hours. At the end of the first year, we will be better prepared to present a comprehensive article for perusal. At this stage, we are limited in what can be stated other than that all signs look good for a successful first year of the project.

(Note: the device referred to and described in BPR 10-36 is an adaptation of a helmet-mounted gunsight system for military pilots. As adapted it would determine the locations of visual targets on a passive target board by sensing the wearer's line-of/sight. The data could, eventually, be used to control devices such as an electric typewriter, environmental controls, voice synthesizer, etc. — Editor)

This concludes the "Sensory Aids" section of the VA RER&D Service Progress Reports, except for **four reports on projects related to blindness** which you will find on the last two pages of the report from the VA Rehabilitation Engineering R&D Center at Hines VA Medical Center. (Page numbers will be 13 and 14 higher than this page.)

Maxillofacial Restorative Materials and Techniques

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Summary and Introduction

Research and development, with direct clinical application, is continuing according to the objectives for six projects outlined in the Comprehensive Development Plan (1). The principal material of this plan since its inception has been polydimethyl (PDM) siloxane processed to approach the strength and elasticity of tissue. The plan provides for six projects, namely; product development, fabrication, pigmentation and cosmetic matching, toxicity test development, field (clinical) participation, and production. The ultimate goal is to assure safe and effective prosthetic devices with detailed documentation on performance standards, good laboratory procedures (GLP) of testing, and good manufacturing practices (GMP).[a] The ultimate aim is to comply with these requirements, while at the same time providing continuous supply of PDM siloxane through the Veterans Administration hospitals and affiliating medical centers.

In the area of being effective and durable, the product development project is providing important leads toward enhancing the extensile properties based on intensified blending of the PDM siloxane components, namely the pre-polymer and oligomer. These leads are translated into the procedures for the GMP.

The fabrication project is developing engineering design of inexpensive moldings larger than the limited dental mold sizes.

In the area of being safe to human tissue in the clinical sense, the human excised donor (HED) tissue culture test development and production lot testing of PDM siloxane[b] has advanced to a biocompatibility test proposed for panel review and approval by the American Society for Testing and Materials (ASTM) through its F04 Committee on Medical and Surgical Materials and Devices. Several competitive cell culture techniques based on use of animal-derived cells and animal-derived whole serum are under similar review. The HED system is believed to

[a]From the beginning of this project, programs were designed to comply with existing regulations of the Food and Drug Administration requiring data and documentation of performance, laboratory procedures and good manufacturing practices as prescribed by the Medical Devices Amendment of 1976.

[b]Biocompatibility testing procedures described in progress reports in BPR since the Fall 1976 issue (BPR 10-26) have included methods in which tissue from a specific patient was cultured in contact with flashings from the molding process of the actual prosthesis intended for that patient. More general procedures have employed stored human tissues of various types from patients of various ages, conditions, etc., for batch-testing of PDM siloxane and for comparative biocompatibility testing of a range of alternative materials.

be desirable on grounds of human relevance because of the use of species-homologous tissue cells and serum systems in contrast to the conventional mixed-species cell and serum (animal) systems.

During the period of July 1 to December 31, 1981, advances have been made in using selected cell growth factors separated from dialyzed human serum from out-dated donor blood (2). The concept of the HED system, initiated some 4 years ago, is gaining attention in publications appearing from European cell culturing laboratories, one of which in particular emphasizes a need for homologous species-specific serum factors in cell culturing (3).

While tissue and cell culture assays have been in use for nearly two decades, the HED tissue culture testing program (1) has anticipated by several years the increasing focus on replacing animals for studying and routinely evaluating the safety or toxicity of a biomaterial to human cell physiology. The current animal welfare movement (4) is calling for alternatives to the use of animals, with pending Congressional action (HR 556) for establishing a center for study of such alternatives (5) in order to minimize use of animals for testing, notably testing for toxicity and tumorigenicity.

The clinically-relevant field participation project continues to serve the VA and non-VA centers, not only in supplying the PDM siloxane stocks but also in providing on-call technical assistance, and evaluation of quality of the moldings made by the participants.

I. Product Development

The research and development tasks are being directed toward (i) developing performance standards in compliance with FDA requirements and (ii) maximizing the cross-linking and chain-branching mechanisms (6) for enhancing the strength/modulus (S/M) quotient, which has served as the principal criterion of biomechanical compatibility with physiological tissues.

Performance standards— This is a primary obligation in consumer protection, assuring that the prosthetic device is biomechanically safe and effectively durable. The standards must anticipate, in addition to the initial biomechanical properties, the changes in the specified properties that would take place in the physiological environment, such as would be determined by implant retrieval analyses (7). It is incumbent upon production to devise and select test conditions replicating aspects of the chemical environment, in order to provide reasonable assurance of biocompatibility and endurance when exposed to the expected biochemical environment of human tissues. (The selection has been to use glycerides to replicate the internal lipid action model, and lactic acid to replicate and serve as the external (dermal) exudate substrate model.)

Additionally, the performance standards include performance in sterilization by autoclaving, and disinfecting (Hypochlorite) for hygienic maintenance.

The performance standards are based on accelerated conditions in order to compress the time scale to a matter of one or two days of exposure. This is done by simply adjusting the test temperature to 100° C. for a period of 24 hours. Such accelerated testing, including cyclic room and high temperature testing, is common in consumer product testing (8).

Product Improvement— Presently, a three-roll mill is used because it is the simplest equipment and a ready means for accomplishing the cross-directional shearing for molecular orientation. The resulting PDM siloxane has attained a strength-to-modulus in the range of 6/1 compared to human tissue range of 12 to 20 (9). However, elastomer technology has other means for compounding or blending, usually reinforcing, that are in common use, e.g. by toroidal (torque) shearing in such blending equipment as Banbury mixers. In a joint engineering research program at Drexel University (10) a series of laboratory runs were arranged for the purpose of achieving higher S/M quotients along with enhancing the chain-branching mechanism (6) for biomechanical durability. Table 1 summarizes the principal tensile characteristics comparing the roll-milling and the toroidal (plastometer-Drexel) or screw blending methods of oligomerization. The two methods, as shown by marked differences in the tensile constants, apparently impose, after molding, profoundly different kinetic rates of cross-linking versus chain-branching. Based on the consistently higher S/M Quotient throughout the range of catalyst level, the toroidal oligomerization can be said to be more effective toward approaching the physiological S/M quotient range of 12-20 (11).

Prosthetic materials are dependent upon the ready supply of designated grades of commercial ingredient materials in the case of this project, a selected prepolymer grade from one manufacturer and a selected oligomer from another. While these grades have been available for many years as prime rather than variously compounded chemical forms, there is always the risk of their being replaced or discontinued by the manufacturer as has been the case with a dozen or so earlier forms of silicones, polyvinyl chloride, polyurethanes, and many proprietary forms of undisclosed chemical identity. Should this happen, this project has included stand-by evaluation with at least one alternative grade of prepolymer (12).

II. Fabrication

In response to frequent requests for pressure molding of large size prostheses beyond that of dental prosthetics limited to 3½ to 4 inches in any one orthogonal dimension, a rectangular box mold described previously (13) was designed and constructed from inexpensive 1-½ x 1-½ inch angle iron. The design can be used in a Carver Press with one dimensional limit of 7¼ inches while the length and height can be as much as 12 inches by 12 inches.

It is expected that the forming descriptions will attract the professional medical sculptors and technicians to assume some of the orofacial reconstructions as well as other anatomical reconstructions. This technical know-how is intended for presentation at a forthcoming national meeting of the Association of Medical Sculptors, July 4–7, 1982, at New York. Some of the Association's membership has expressed interest in making prosthetic devices from PDM siloxane.

III. Pigmentation

Although the standardization of the internal pigment form of the six-shade panel of internal pigmentation has

been accepted generally in the Field (clinical) Participation program, periodic monitoring is conducted on changes in coloration due to aging and exposure to light. From random checks on pigmented test plaques made as long as 30 months ago, there has been no measurable evidence, using the Hunter digital color difference system (14), of changes in carotene yellow replication and the arterial red replication of the internal coloration.

The extension of the six-shade panel to two additional melanoid examples, for Afro pigmentation, is scheduled to be resumed in the next quarters.

TABLE 1
Effect of different milling operations, calendering versus toroidal (screw) on tensile constants and S/M Quotient.

Composition: 80/20 Prepolymer/Oligomer Ratio
Catalyst Level: As indicated
Molding Conditions: 100 ± 5°C. for 2 hours
Tensile Properties: ASTM D-412

Catalyst level (pph)	Milling Unit	Type of Shear	Tensile Constants			
			Modulus lb/sq in	Strength lb/sq in	Elong'n %	S/M Quotient
0.5	3-Roll Mill*	Unidirectional**	59.1	291	941	4.9
	Plastometer	Toroidal	50.6	571	571	11.4
	(screw)					
1.0	3-Roll Mill	Unidirectional	84.9	386	386	4.6
	Plastometer	Toroidal	72.6	619	619	8.2
	(screw)					
2.0	3-Roll Mill	Unidirectional	131	484	484	3.7
	Plastometer	Toroidal	103	634	634	6.0
	(screw)					
3.0	3-Roll Mill	Unidirectional	143	326	387	2.3
	Plastometer	Toroidal	121	567	404	4.5
	(screw)					

* Present production mill (Kent) in this project

** Calendering in one direction but alternately changing to transverse for extensive cross-shearing.

Comments: The toroidal (screw) blending results in reduced modulus, increased elongation (except in one single case with low catalyst level), and markedly increased S/M Quotient, all highly favorable improvements for biomechanical properties.

IV. Toxicity: Test Development and Standardization

Cell culturing techniques are gaining increasing prominence in the assessment of boimaterials when used in prosthetics and as implant materials. A.S.T.M. Committee FO4 (Medical and Surgical Devices) has scheduled a cell culture symposium for this spring in which 11 participants will describe the assays used in his or her laboratory (15). Since the early stages in this project's work with in vitro culturing of isolated cells, scores of culturing media have been devised by empirical selection of essential salts, amino acids, vitamins, hormones, and other factors, along with the use of serum, notably fetal calf and bovine in general. The latter always presents the risk of variable presence of ingested agri-chemicals, and regional variations in animal feed and veterinary prophylaxis which must always be suspect as toxic contaminants in such animal serum. Such empiricism has produced only a few successes in replicating the morphology of the normally (in vivo) derived primary cell forms, but led rather to entirely new species of irreversible cell lines or strains. Generally, cell culturing led to fibroblast stages that stopped at that stage and could rarely be cultured to form mature, organized cell structures of the epithelial form with which prosthetic devices and implants would come in contact.

In order to overcome that lack of replication of the in vivo cell organization, this project has been directed toward developing a test system using species-homologous human cells, with human serum specially prepared by dialysis to remove ingested potential toxicants followed by separation of the specific cell growth and development components from human serum. A purpose of this research is to see if this homologous cell-and-serum approach actually imparts a higher degree of human relevance in assessing toxicity or biocompatibility of PDM siloxane to human tissues. The focus of this project, which is crucial to the release of PDM siloxane to clinical prosthetics, has been on the separation and characterization of protein components of human serum for tissue cell growth augmenting a comprehensive chemically defined medium. This, in turn, is to induce the cultured primary cells to propagate in a manner that replicates cell types of the excised human tissue to which PDM siloxane is to come in contact. A three-way approach is being applied, which includes (i) separation and identification of cell growth factors from prepared human serum, (ii) standardizing and qualifying the test system, and (iii) applying biochemical and biophysical monitoring of the tissue culture test for eventual approval.

A. Separation and Standardization on Human Cell Growth Factors — Currently, human serum is eluted from glass microbead columns with a series of buffered solutions. Particular attention has been accorded to surface treatment and conditioning of the glass microbeads, to assure reproducibility of the eluted fractions so that they may be specified for use in our tissue culture testing system as currently proposed to ASTM. Glass surfaces are known for their sensitivity to monovalent (sodium and potassium) and bivalent (calcium and magnesium) ions such as exist in serum. The specific ions in serum can be expected to

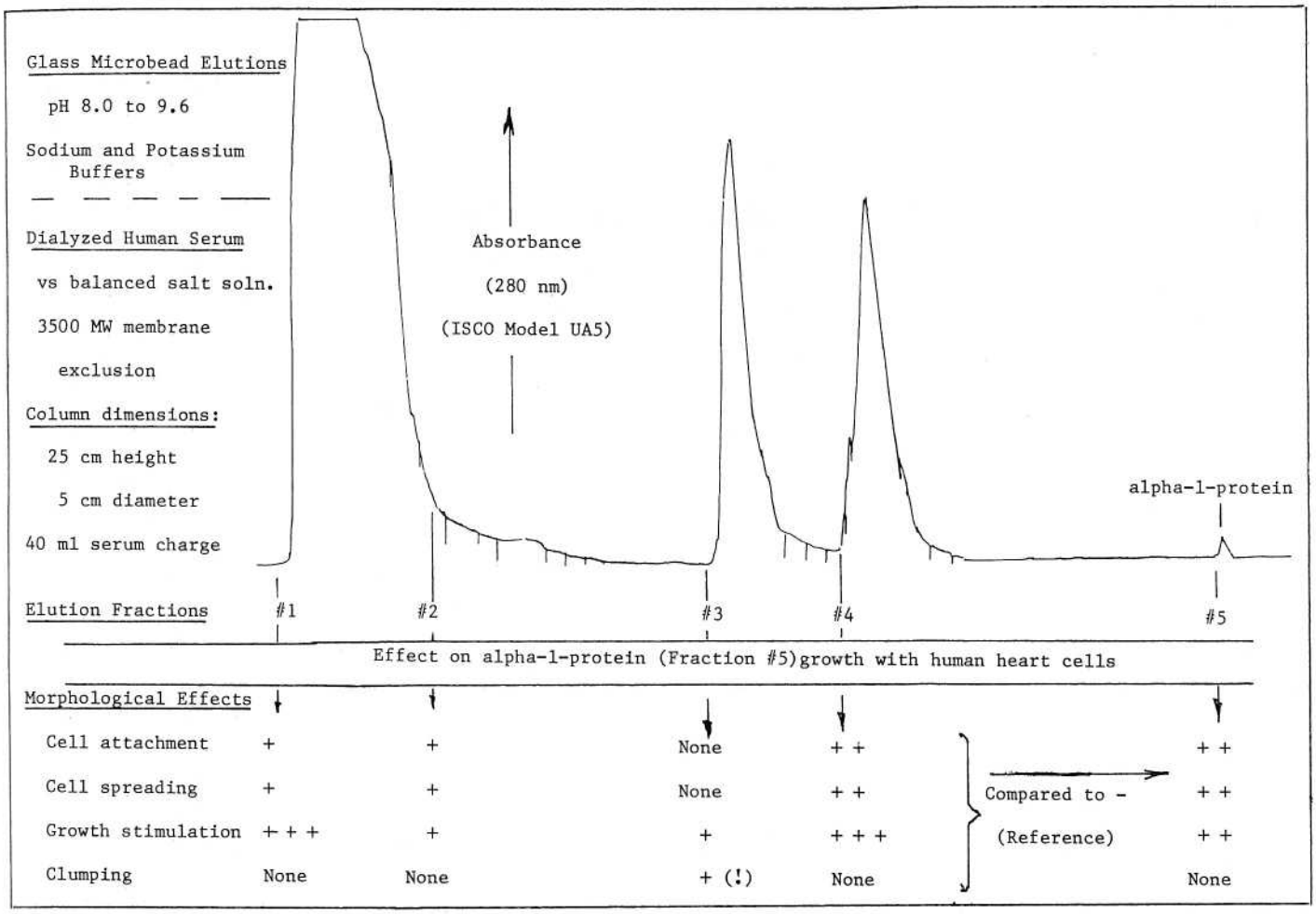


FIGURE 1
Assessment of protein components separated by dialyzed human serum in terms of specific morphological growth and organization. (+, ++, +++, indicate level of activity.)

impose profound biochemical and biophysical effects on the function and development of intercellular organizations, as well as affecting the structure of protein complexes (Fig. 1).

Accordingly, glass microbead column separations of specially dialyzed human serum have been conducted on a broadened scale. This three-phase project uses: first, unconditioned glass microbeads; second, beads conditioned with bivalent calcium (Ca) ions; and third, beads conditioned with EDTA, a chelating calcium-depleting agent. This approach delineates the deliberate or chance role of calcium ion which is an active complexing agent on serum proteins.

The separated glass-microbead-elution fractions are characterized by scanning polyacrylamide gel electrophoresis, using the recently acquired Varian Cary Spectrometer (Fig. 2). With this spectrometer, the conventional photographic representation of the gel electrophoretic separations (Fig. 3) are thus accorded more discriminating peak profiles which can be quantitated (Fig. 4, 5, 6). This technique is being developed as a means for determining morphogenetic activity as well as quantitative titers of the cell growth factors.

The plethora of cell growth factors, cell attachment factors, epitheal and nerve growth factors, cell hormones, and specific nutrients are emerging as needed supplements in tissue culture. The present program is being directed toward isolating these factors from human serum based on ionic elution fractionations at controlled pH levels, as described. The elution fractions (Fig. 1) are then tested with the qualifying human heart (Girardi) established cell line in a chemically defined medium (16). The tests are intended to locate and separate those serum elutions that would induce enhancements in cell attachment, cell spreading, and growth stimulation, from those that would in some way be detrimental or toxic to the cultured cells or counteract the action of the growth-promoting factors.

In line with the above separatory endeavors, cellular activities of the elution fractions, numbering at least five at present, are tested for biological activity and represent the five different ionic, sodium buffer, and potassium buffer fronts, eluted through the glass microbead column. Fraction 5 shown in Figure 1 constitutes the principal growth factor, alpha-1-protein, utilized as the reference (control) medium to which are added separately the other preceding eluted serum protein fronts. The activity of each of the preceding elution fractions is then assessed by the response of the established human heart cell line for four indicated cell growth features, namely: attachment, spreading, growth stimulation, and clumping.

As summarized in Figure 1, the pre-

FIGURE 2
Scanning a section of a polyacrylamide gel electrophoresis stained pattern with the Varian Cary 210 Spectrophotometer. Sectioned gel emplaced in a special Teflon carrier, inserted at (A) in a light-tight enclosure, is being positioned for travel across a directed beam of predetermined UV wavelength. Characteristic peaks of protein entities from dialyzed human serum, as described in Figures 5, 6, and 7, are thus recorded (B).

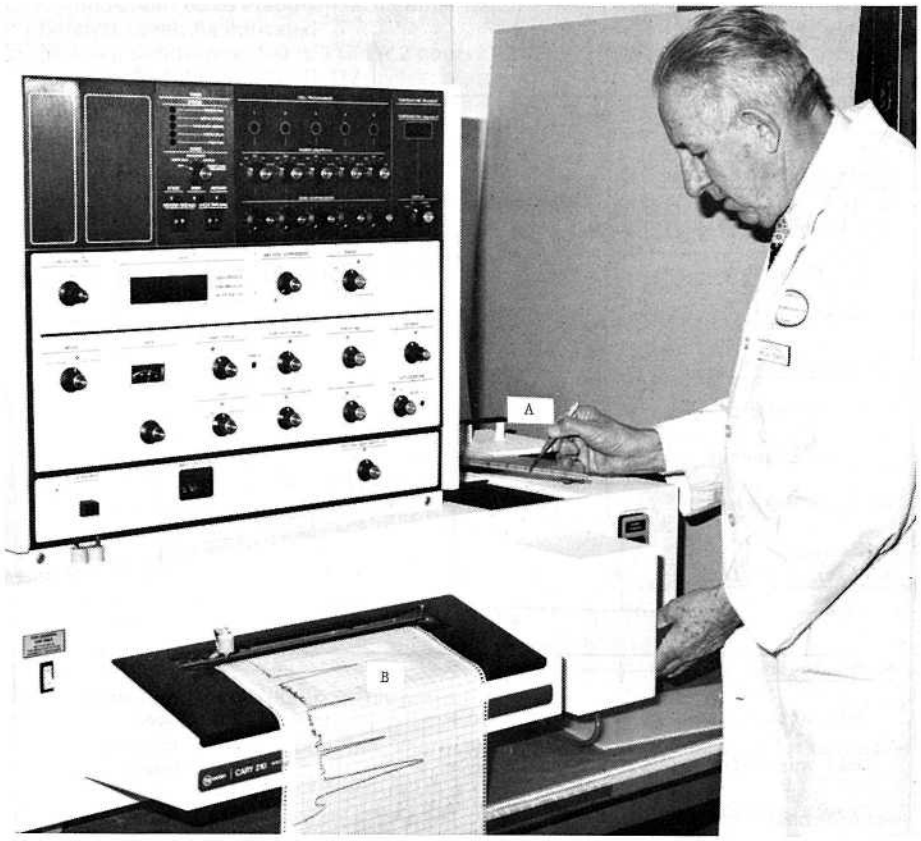
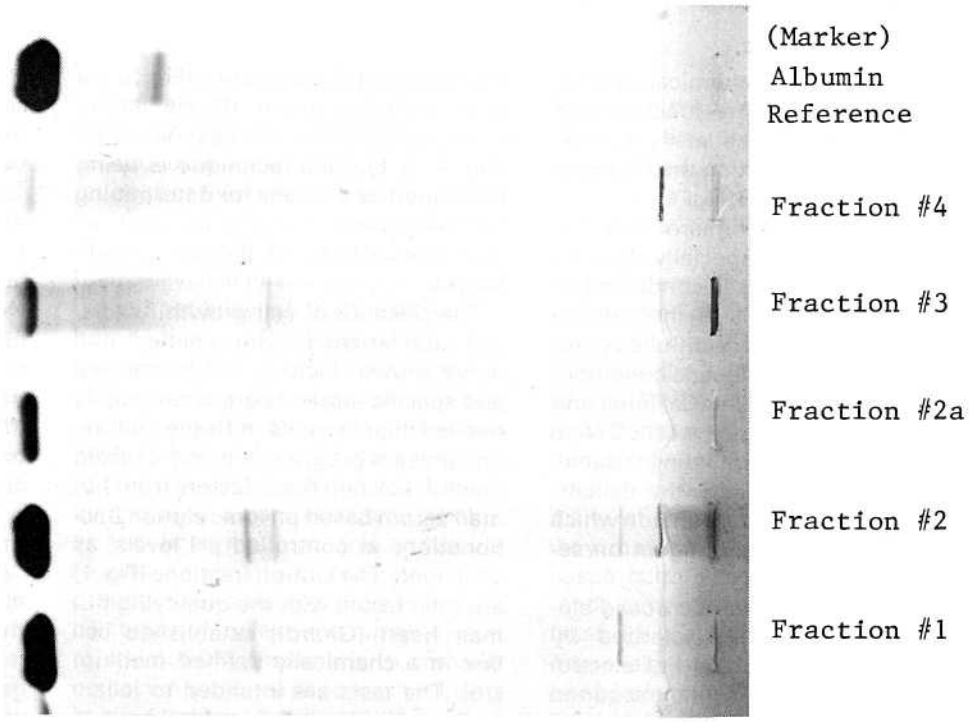


FIGURE 3
Series patterns of polyacrylamide gel electrophoresis of dialyzed human serum elutions (Figure 2) from which separate cut-out sections are scanned in the Varian Cary 210 Spectrophotometer for characteristic protein entities as growth factors which are being assayed for cell development activity with established line of human heart cells for test qualification (medium quality, reproducibility, etc.) preceding definitive morphological studies with primary H E D tissues. Fraction #5 comprising the human alpha-1-protein growth factor is not shown in the above series, but is included in on-going separations and biological cell assays.



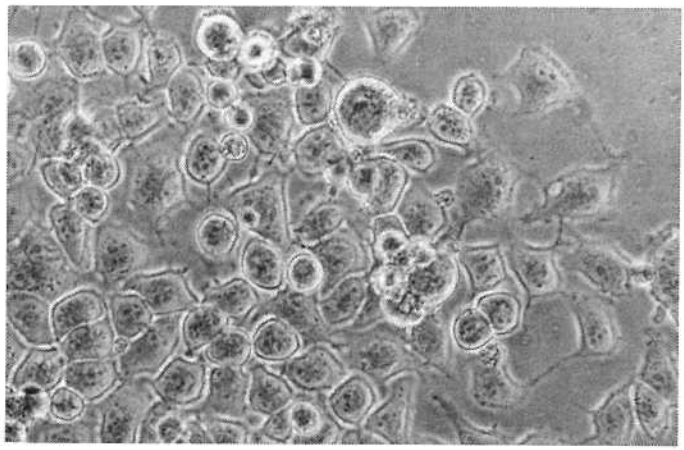


FIGURE 7
Effect of Fraction 5 containing alpha-1-protein serving as reference (control) to determine the effects of other fractions of eluted dialyzed human serum on growth of established human heart (Girardi) cell line. Test conditions: Holmes A3 chemical medium, 72 hours. (590x)

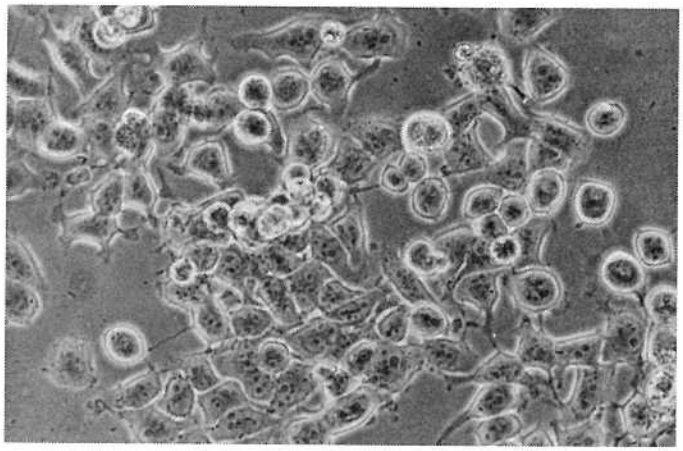


FIGURE 8
Effect of Fraction 1 on growth of established human (Girardi) heart cell line in the presence of alpha-1-protein growth factor (Fraction #5). No adverse effect was noted and there may be some growth stimulation augmented. Test conditions: Holmes A3 chemical medium, alpha-1-protein. 72 hours. (590x)

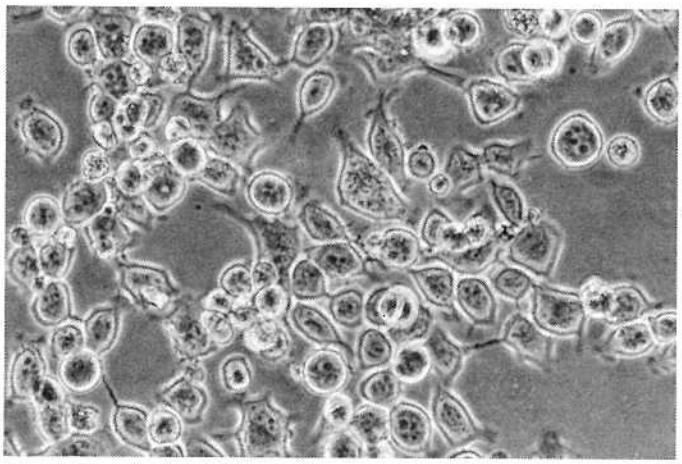


FIGURE 9
Effect of Fraction 2 on growth of established human (Girardi) cell line in the presence of alpha-1-protein growth factor (Fraction 5). No adverse effect was noted. Test conditions: Holmes A3 chemical medium, alpha-1-protein, 72 hours. (590x)

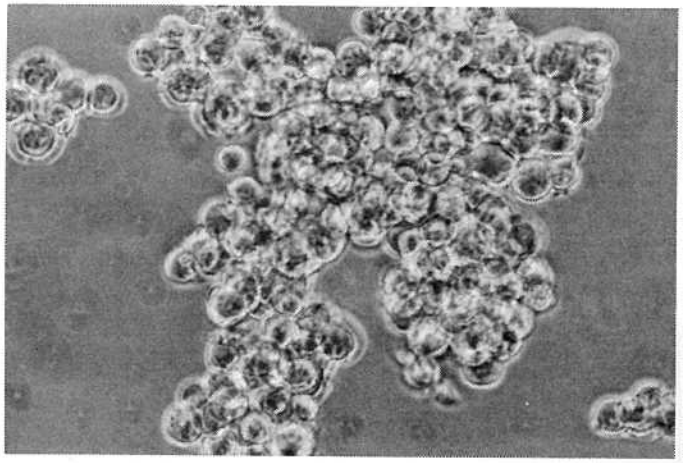
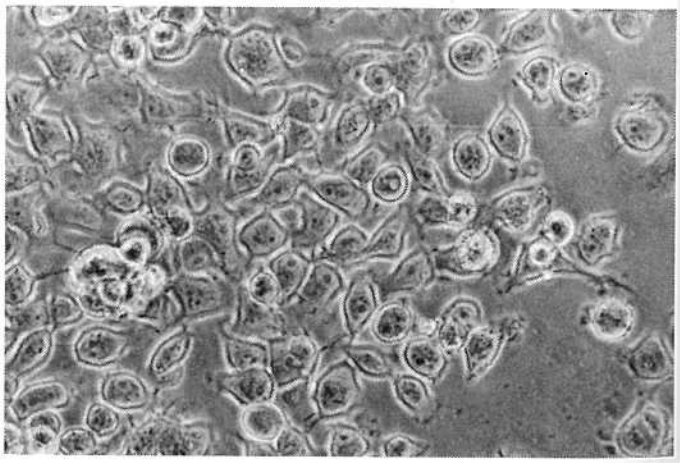


FIGURE 10
Effect of Fraction 3 on growth of established human (Girardi) cell line in the presence of alpha-1-protein growth factor (Fraction 5). Marked changes, possibly severely adverse, were imposed, notably, pronounced clumping along with lack of cell attachment and cell spreading. Test conditions: Holmes A3 chemical medium, alpha-1-protein, 72 hours. (590x)

FIGURE 11
Effect of Fraction #4 on growth of established human (Girardi) heart cell line in the presence of alpha-1-protein growth factor (Fraction 5). Apart from no adverse effect such as is noted with Fraction #3, there is no adverse growth effect and possibly some augmented growth stimulation. Test conditions: Holmes A3 chemical medium, alpha-1-protein, 72 hours. (590x)



ceding eluted protein fractions when added with Fraction 5 alpha-1-protein had varying effects on cell growth and organization. (The effect of Fraction 5 alone on cell activity is shown in Figure 7.) In combination, the initial elution front, Fraction #1 (Fig. 8) appears to enhance growth stimulation only. Fraction 2 (Fig. 9) appears to have no significant effect, but may impose a slight detrimental effect. Fraction 3 (Fig. 10) appears to be detrimental to the action of alpha-1-protein with regard to cell attachment and cell growth and particularly in inducing potentially undesirable cell clumping. Fraction 4, whose cell activity is shown in Figure 11, appears to provide some growth stimulation without affecting the other three cell-growth features.

This preliminary assessment with the established human heart (Girardi) cell line is a valuable means for qualifying the proposed ASTM test standard, for two reasons. Firstly, the effect on the quality, in terms of activity units of titer of the alpha-1-protein, can be obtained within the short time period of the test, namely, 72 hours. Stability (shelf life) has previously been determined to be 3–4 months at 0°F and up to 2 years at −70°F. Secondly, when applied to primary human tissues, alpha-1-protein is not sufficient to sustain these tissues and requires supplementing with other fractions of the human serum. Currently, the reference tissue cell has been successfully maintained for 6 months using whole dialyzed human serum. Each serum lot, however, may not give exactly the same cell growth response. (The latter problem has already been experienced in our laboratory and is generally the case with bovine serum which is highly variable lot-to-lot.) It is therefore necessary for the proposed ASTM test procedure to minimize this problem. Data obtained from the above separation procedures should enable one to devise a method for preparing human serum of superior quality for use in the testing of prosthetic materials in tissue culture.

It is appropriate to note that advances in tissue culturing, and especially definitive cell culturing, are emphasizing and indicating that the total amount of serum protein is in the order of micrograms per ml of media which is just about the estimated range in the current series of tests. Considering the removal of low and middle molecular-weight serum components by dialysis with up to 3500 molecular weight exclusion, and the serial dilutions during the microbead elutions, it appears that the activity of the growth factors is effective in the range of nanograms per ml of medium, as for instance with the alpha-1-protein. As members of one leading group of cell biologists declare (3, 17 and 18), the cell culture requirement for serum protein is utilization of micromolecules for the performance of specific regulatory functions. To prove this, it is first necessary to isolate and characterize the specific roles that these factors play in promoting cellular growth. Conversely, it is also necessary to isolate those factors in human serum that are likely to negate the activity of the growth factors, or that even prove to be antagonistic to the cells themselves. This advisory (and even a caveat) against dependence upon the unpredictably variable quality of fetal calf or bovine serum, results from experience gained during the effort by this group to provide the proposed ASTM test method with isolated and titer qualified growth factors separated or eluted from serum.

B. Tissue Culture Standardization—Currently, two categories of human cell cultures are being maintained in this laboratory. The human heart (Girardi) cell line is used to evaluate the separation of human growth factors from dialyzed human serum lots. Primary human cultures are maintained for the standardization of test methods used to assess safety, in terms of noncytogenicity, of production grades of PDM siloxane including the fabricated prosthetic forms. Cell cultures originally obtained from patients are primarily cultured from explants and sub-

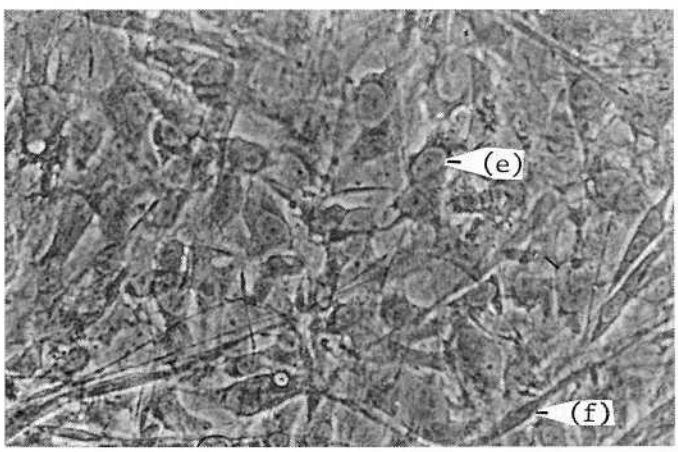


FIGURE 12
Primary culture of mixed cell types grown from human excised donor tissue (finger) section in A3 chemically defined medium with 10 percent processed (dialyzed) human serum. This tissue culturing demonstrates the concomitant growth of cells ranging from fibroblasts (f) to well-formed epithelial (e) organizations, along with other cell forms, such as also shown in Figure 13 of an isolated tissue growth. This type of culturing is of higher order of relevance to biocompatibility than that with single-type established cell lines. (590x)

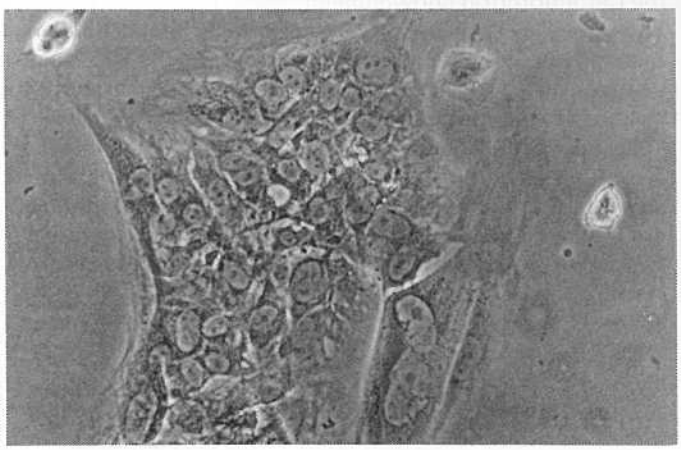


FIGURE 13
An isolated colony of epithelial cells, trypsanized from the primary culture shown in preceding Figure 12, and grown in A3 chemically defined medium with 10 percent processed (dialyzed) human serum for 24 hours. This technique, developed purposely for tissue culturing with integrated parent cell types up to mature epithelialization, constitutes the thrust of the human excised donor tissue testing system procedure for biocompatibility, as currently proposed to A.S.T.M., of prosthetic materials and devices for safety to human tissues. (590x)

sequently split several times in order to provide an appropriate number of cultures which are then used to evaluate the various forms of cell development features as described in the previous section.

The tissue culturing procedure involves isolating pure colonies of specific cell types, so that not only will the serum growth factors be tested on mixed cell populations but also on cultures containing primarily: fibroblasts, epithelial, myogenic, or other cell types, as seen in Figures 12 and 13. In this manner, effects on specific cell types and combinations of types can be tested. This will insure the best combination of serum fractions in terms of cell growth and organization for each tissue type. It may be necessary to anticipate differential effects, depending upon the type of cells in culture. The HED test system is intended to include appropriate specification of human growth factors and any chemical additions in a medium required to provide human-relevant interpretations.

Application of Flow Cytometry.

In order to provide a quantifiable assessment of the test system,including growth curves of the isolated cell types and quantitation of cell types in mixed cultures, flow cytometry (19) is available with the recent procurement of the Cytofluorograf shown in Figure 14. The optical system is shown diagrammatically in Figure 15. Flow cytometry involves passing a suspension of cells in an aqueous medium through a capillary in such a manner that, as each cell interrupts the laser beam, the ensuing absorption, scattering, and reemittance of light is counted and registered in a display of histogram distributions. This concept is ideally suited for our primary cell culturing in which the different cell types, as for instance with a selected group of three, can be analyzed. This provides a means for determining the best cell types or combination of types and their appropriate growth factors. There are, however, technical adjustments especially in determining the best method of (i) releasing the adhering cultured cells from the culturing flask, (ii) providing for complete dispersion of the detached cells, and (iii) devising procedural details on count levels and selecting specific fluorescing agents. The unit has been procured from the VA Central Research Instrumentation Program (CRIP) and is being adjusted to operate for this range of versatility. Preliminary countings of the established heart cell lines are in progress to work out these three areas of quantitative cytogenicity.

V. Field, Clinical Participation

Requests for PDM siloxane for orofacial prosthetic reconstructions have come from a total of 53 clinics (including both VA and non-VA, with recent requests from Israel and Chile). For this participation, more than 300 one-pound units of mostly pigmented PDM siloxane have been provided, but including a score of non-pigmented stocks for special internal orofacial reconstructions.

There are frequent requests for technical assistance in molding enlarged forms, such as orbitals and extremities (hand and foot) for which the simplified, inexpensive framing mold has been developed as described in previous reports in BPR (13). Technical assistance is believed to be important not only for sustaining interest in orofacial prosthetics, but also for recruiting medical sculptors into the molding of large-dimension prostheses, etc., of PDM siloxane. There is keen interest in the unusual features of PDM siloxane, hitherto not appreciated in the prosthetic field, namely its soft, flexible, "life-like" tensile characteristics and a tear strength that is from two to four times greater than that of skin tissue. Thus, there is a need to provide technical service to those unfamiliar with enlarged dental-stone molding and in fashioning reinforcing frames for the fragile stone, plus providing assistance in organizing an appropriate molding laboratory. A procedural manual for medical sculptors is being considered.

A three-day symposium and workshop for restoration technicians was held at this Center, September 9–11, 1981 under the joint sponsorship of the Rehabilitative Engineering R&D Service and the Office of Academic Affairs, Veterans Administration Central Office. Presentation included information on the status of safe and effective compliance standards,demonstrations of innovations in molding techniques, and instruction in fabrication of artificial eyes.

Acknowledgement

The authors wish to acknowledge gratefully the generous assistance and contributions of continued supplies of human blood plasma from the Blood Bank of Delaware, Wilmington, Delaware, a contribution of significant monetary savings. Likewise the assistance and contribution of chemicals and separatory absorbants for serum protein separations by the Alfred I. du Pont Institute of the Nemours Institute, Wilmington, Delaware, is gratefully acknowledged.

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FIGURE 14
Developing a cytometric method for counting and differentiating cell species from cell and tissue culturing by absorbance and scattering of fluorescent cells passing across a laser beam as shown schematically in the next figure (Fig. 15). Samples of cultured primary and established cells, for which a special technique of dispersion is being developed, are introduced at (A) and flow through the pipet (B) through which the laser beam makes the counts and differentiations which are then displayed on the oscilloscope (C). This technique is espected to provide discriminating counts of the diverse cells developing simultaneously during tissue culturing, and to differentiate quantitatively between viable and non-viable cells as an indication of non-toxicity and toxicity, and between transformed and non-transformed neoplastic cells utilizing the myriad of fluorescent techniques available to make similar differentiations subjectively.

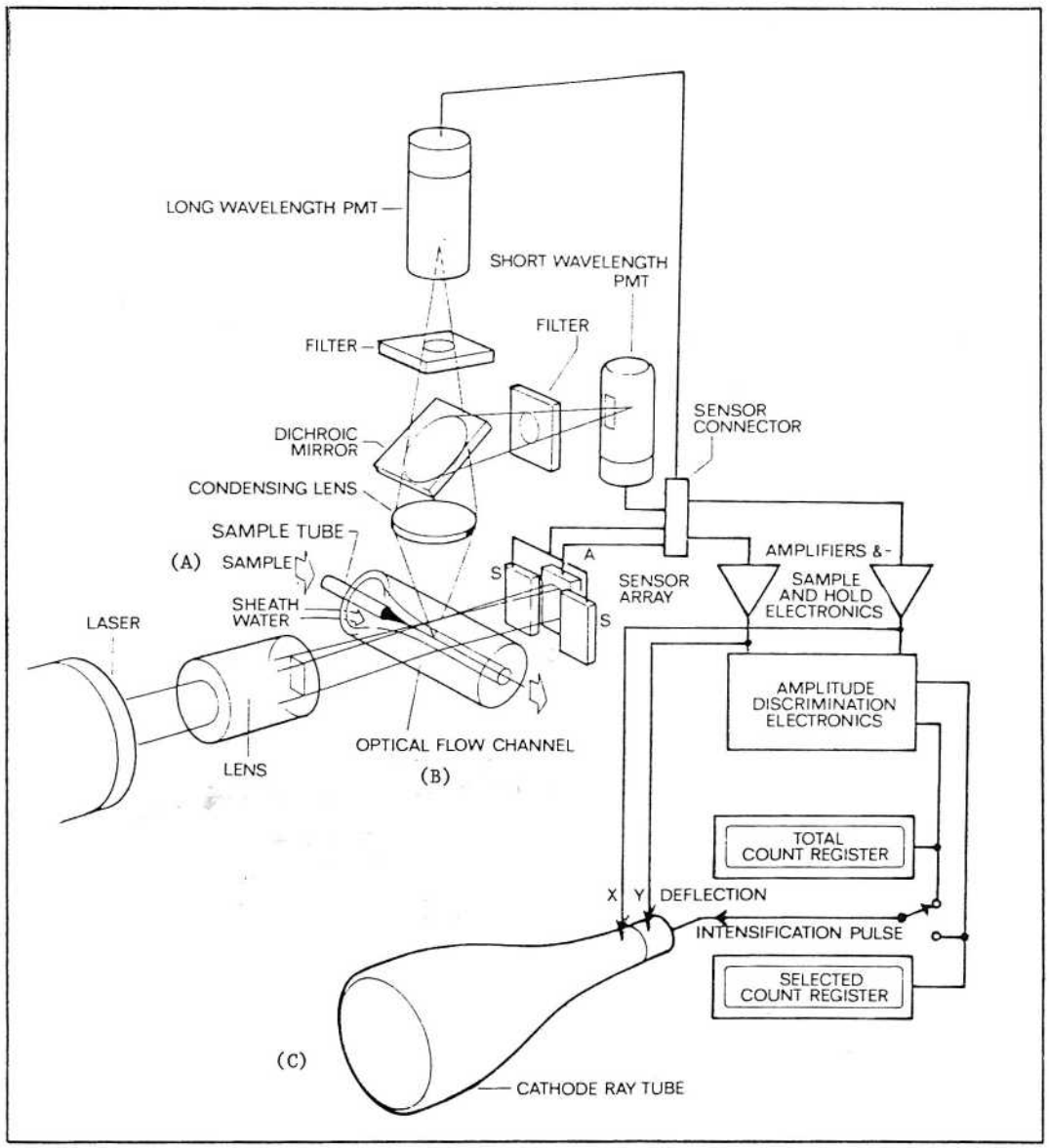

FIGURE 15
Schematic outlay of the Cytofluorograf depicting the passage of the laser beam through the channel carrying the individual cells from the sample introduced at (A) through the pipet (B) serving as optical flow channel, thence counted and differentiated for registration and display by the cathode ray tube (C).

are being created and displacement measured. Results are being obtained but the data are still insufficient to draw conclusions.

More data will be obtained to make the measurements statistically significant, and the angle of the facet joints of the cervical spine vertebrae will be measured.

A Methodology for Identification of Non-Linear Constitutive Parameters of Biological Material

A. Patwardhan, Ph. D., and R. Vanderby, Ph. D.

Human spine is a complex 3D structure varying somewhat from individual to individual, composed of relatively rigid bony vertebrae with interlocking facets of somewhat variable angles, with vertebrae separated by tough, resilient discs and tied by strong fibrous bands. Each of these materials displays nonlinear relationships between tensile or compressive loads and resulting deformations.

The resulting overall reaction of the spine to loading can be approximated by modeling the spine in one of three ways: (i) a continuous curved structure of average elasticity, (ii) a model of lumped rigid elements with flexible connecting elements, each with averaged properties, or (iii) a model with more finely subdivided finite elements, permitting assignment to each element of different size, mass, stiffness, and boundary conditions at connections to its neighbors.

The response of the spine as predicted by such a model is dependent upon the model parameters which define the stiffness properties of each element. The validity and applicability of such models can be improved significantly if the nonlinear constitutive properties of these elements can be adequately described. The purpose of this study is to develop a methodology to identify the nonlinear constitutive parameter describing the nonlinear behaviour of the biological material. The method will be demonstrated by identifying such parameters for the components of two spinal segments.

The finite element method permits, with increased complexity and computer use, assignment of nonlinear properties, such as stiffness sharply increasing with displacement (e.g. rubber bands, most biological tissues). In turn, such mathematical models permit use of physical tests of entire structures to estimate the nonlinear engineering properties of the biological materials involved.

The methodology being developed utilizes the finite element model as a part of an optimization algorithm using repeated trials to approach a solution. The nonlinear properties of each element are defined in terms of the unknown constitutive parameters. The parametric optimal design (POD) formulation expresses the objective function and the functional and regional constraints in terms of the unknown constitutive parameters, and the nodal displacements. At any iterative stage of the POD problem, the state of the system (i.e. the nodal displacement) is evaluated using a nonlinear finite element procedure which utilizes strain energy functions to represent constitutive relationships for large displacement soft tissue. The optimization algorithm utilizes the design sensitivity analysis to evaluate, at each iterative stage, the sensitivity of the objective function and the constraint functions with respect to each of the unknown constitutive parameters. The information derived from the sensitivity analysis is then used in conjunction with the gradient projection algorithm (steepest descent method with constraint compensation) to solve the POD problem.

Following the development of the above algorithm, a series of experiments will be performed on human spine motion segments to obtain the force-displacement functional description of the motion segments. The inverse boundary value problem will then be solved using the aforementioned methodology to identify the nonlinear material parameters.

A Cervical Spine Orthosis

A. Patwardhan, Ph. D., R. Vanderby, Ph. D., and L. Kynast

The purpose of such an orthosis is to diminish head and neck tremors seen in patients with the primary diagnosis of multiple sclerosis affecting the cerebellum. The need for such an orthosis was identified when the Neurology Service at the VA Hospital, Hines, consulted the RER&D group regarding such a patient. The patient's activities serving basic needs such as self-feeding, reading, etc. were severely hampered by the tremulous head and neck.

A prototype of the "first generation" cervical spine orthosis was designed and fabricated at the RER&D Center. The basic concept behind the device was to reduce the tremors using a combination of capillary-flow hydraulic damping and compression springs. An existing four-post orthosis was modified by replacing each rigid post by a damped piston-cylinder arrangement in series with a compression spring. Four ball and socket joints were used to allow freedom in rotation. The "flexible" posts themselves allowed freedom in flexion-extension and lateral bending. The existing mounting of the four-post orthosis was replaced by a body cast jacket and a cross-strap over the head to achieve better performance.

A pre- and post-orthosis evaluation of the patient was made using recording on videotape. This analysis revealed a significant reduction of the head-neck tremors. This analysis also suggests that several modifications can be made in the first design from both mechanical and cosmetic design points of view. The patient is currently using the first design and will provide the necessary feedback for future modification.

Loadbearing Characteristics of Lumbar Facets

A. Patwardhan, Ph. D., R. Vanderby, Jr., Ph. D., and M. Lorenz, M.D.

A better understanding of the loadbearing characteristics of facets may provide some biomechanical insight into facet joint instability and degeneration which have long been implicated in the etiology of low back pain. The purpose of this project is to experimentally (in vitro) determine the facet loads, contact areas, and peak pressure values at the facet joints under simulated physiological loading conditions.

A pilot study was carried out to measure the induced loading at the human lumbar facets due to varying amounts of compressive axial loading simulating the physiologic loading on the spine in the supine and upright stand-

ing postures. The compressive loading was applied to the spinal segments in neutral and extended positions. The segments were tested in the normal state as well as after left facetectomy. The contact pressures at the facet joints were recorded on a pressure sensitive film.

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A Finite-Element Model of a Human Spine Motion Segment

R. Vanderby, Ph. D., and A. Patwardhan, Ph. D.

A finite element model is needed for the detailed description of the load-bearing characteristics of each anatomical component of the spinal motion segment. Such a model, once developed, can be used to study the behavior of a spinal segment under normal conditions and to identify quantitatively the abnormal loadings leading to spondylolysis and spondylolisthesis, facet fractures and other stress-related abnormalities.

The existing finite element codes are being modified to incorporate a static condensation procedure, to eliminate excessive degrees of freedom in the numerical solution of the finite element model. This will lead to improved numerical efficiency in the iterative solution process.

A new technique is being developed for rapid modeling of the complex 3-D geometry of the vertebral bodies, utilizing an instrumented linkage transducer system to digitize the surface points and then generating the internal nodes using advanced 3-D mesh generating software.

The above tasks will be completed and tested, and the experimentally obtained data will be used to simulate the normal and abnormal loading conditions leading to the aforementioned stress-related changes in the spinal motion segments.

Normal Talar Dome Loading Patterns in Simulated Stance Phase

M. Zindrick, M.D., A. Patwardhan, Ph. D., and R. Vanderby, Ph. D.

The purpose of this project is to determine the stress distribution on the talotibia joint during simulated stance phase, using direct measurement with pressure sensitive film.

The loading frame has been constructed. Initial specimens presently are being prepared for testing. Test parameters are identified and experimental protocol has been established. The data analysis technique has been completely developed.

The normal loading patterns during stance phase will be established. Once normals are established, simulated ankle fractures will be produced to determine the effect throughout the stance phase of specific anatomic disruption.

APPLIED NEUROPHYSIOLOGY LABORATORY

Effect of Minute Electric Current on Regeneration of Spinal Cord

T. Khan, Ph. D. and J.D. Jhabvala, Ph. D.

The central nervous system (CNS) has a very limited capacity to regenerate after injury. Failure of the CNS to regenerate its lesioned fibers leads to many neurological disorders. Given the proper environment lesioned central axons may form functional connections. This study is an attempt to determine the effect of minute electric current on regrowth of injured spinal-cord fibers.

We are currently investigating the feasibility and biocompatibility of implanting a chronic stimulation unit into the spinal cord of experimental animals after the contusion injury.

The experimentally injured spinal cord of animals will be chronically stimulated with minute electric currents of nanoampere magnitude. The effects of such stimulation on regrowth of injured spinal fibers will be examined both electrophysiologically and histologically.

COMMUNICATIVE AND SENSORY AIDS LABORATORY

Factors Affecting the Use of Reading Aids by the Blind

B.L. Zuber, Ph. D., John Trimble, Ph. D., and Dave Hislop, B.S.

The blind reader using a reading aid represents an information processing system. Constraints which limit the capabilities of the system may be imposed at various stages: either in the several physiological mechanisms utilized or in the reading aid itself. Using a rational scheme of performance measurement across several reading aids in a carefully selected population of readers, we hope to identify and localize the major constraints in the system.

A prototype monitoring system consisting of text display, modified closed-circuit television system, and special-purpose signal processing electronics has been developed for the purpose of demonstrating feasibility. The system has the capability of tracking a general purpose light-emitting diode (LED) anywhere in the field of view of the television camera. The electronics generates two voltages: one proportional to the horizontal position and one proportional to the vertical position of the LED within the field. When the LED is mounted on the scanning head of the Optacon or on the finger of the Braille reader, hand position can be monitored with a resolution of about one character for the electronic aids, and a fraction of a character for Braille.

The manual tracking patterns of blind readers using the Optacon and Braille will be recorded in separate experiments. Texts will be randomly selected from a set which has been quantitatively graded for difficulty. Reading rates and tracking parameters will be measured and analyzed.

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Development of a Signal Processing Technique for Laryngeal Pathology Diagnosis and Assessment

John R. Deller, Jr., Ph. D.

The objective of this study is the development of a computer-based diagnostic technique for pathologic condi-

tions of the larynx using the acoustics of speech. The work, which was initiated in September 1979, began with a feasibility study to determine whether inherent systems identification properties of two existing technologies (linear predictive coding (LPC) (3,2) and phase derivative pole-zero modeling (4)) could be exploited to classify acoustic anomaly. Considerable variability in the system features relating vocal information for clinical cases led to the development of an approach more oriented to the time domain.

"Closed-phase" inverse filtering (CPIF) (1) is currently being used to obtain an accurate cycle-by-cycle estimate of the glottal volume velocity waveform from which parametric features can be extracted for statistical classification of cases. Eighty-five digitized voice samples with associated diagnoses have been acquired for use in the testing of the classification procedures (5).

Concurrently a careful study of the effects upon the CPIF method of the model violations inherent in pathological speech are being studied for prospective development of improved procedures for volume velocity estimation. The work has engendered two further subprojects relating to modeling of pathological speech production which will aid in the interpretation of clinical results. One paper has been submitted and another is being prepared.

The technique will be applied to clinical diagnosis of pathologic speech disorders.

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Measuring the Performance of Blind Travelers

Rebecca Hollyfield, Ph. D. and John Trimble, Ph. D.

The purpose of this study is to develop a set of gait-related parameters that can be used to assess the mobility performance of blind travelers.

An instrument has been developed to measure the real-time interankle distance. Ten subjects were tested using this instrument: five blind subjects and five sighted (blindfolded) subjects. The subjects were asked to travel a laboratory course containing three basic elements; straightaways, corners, and obstacles. Intergroup and intertrial differences were noted in three gait parameters: maximum interankle distance, step time, and cadence.

Further trials will be run to determine the sensitivity of these measures to subtle changes in mobility performance. Also, gait measures will be made on students in orientation and mobility training. These measures will be correlated with measures of the students' travel habits to see if they can provide a simple, effective way to predict travel performance following training. The new measures will also be used in studies of auditory cues used by blind travelers.

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Spatial Factors Influencing the Legibility of Tactile Forms

J. Trimble, Ph. D.

The intermediate goal is to isolate and quantify the parameters of tactile forms which influence their legibility. The ultimate goal is to use this knowledge to design an effective, low-cost tactile graphic display for the blind.

Two sets of Braille characters were selected for the pilot study. One set comprises those characters easily recognized by a majority of people (Nolan and Kederis, 1969). The other set comprises those characters most often confused by a majority of people (ibid). Spatial fourier transforms were made of both character sets using a coherent optical processor. Preliminary results suggest the legibility of Braille characters is related to their spatial frequency characteristics.

The pilot study will be repeated using a coherent optical processing system with higher resolution. If the preliminary results hold, the set of easily-confused Braille patterns will be transformed in space to improve their legibility. The transformed patterns will then be converted to 3-dimensional forms using holographic techniques. The efficacy of the transformation will then be tested and quantified using psychophysical techniques.

Videotex for Disabled Veterans—Concept Trial of an Emerging Technology

J. Trimble, Ph. D. and P. DiMonte, RPT

The purpose of this project is to study the potential applications of interactive television services to disabled people.

Veterans on the VA Hines Spinal Cord Injury Service have been surveyed to assess their needs for information on their disability. Survey results indicate a possible need for information in six areas: medical problems; wheelchairs, vans and assistive devices; new medical products; organizations for disabled people; personal problems; and, public places with access for disabled people. In collaboration with Field Electronic Publishing, the RER&D Center will implement an interactive television service (KEYFAX) to provide veterans on the SCI Service with information on four of the six topics. KEYFAX will offer timely information on: products for disabled people, organizations for disabled people, public places with access for disabled people, and wheelchairs, vans and assistive devices.

The original survey will be expanded for verification of preliminary results. Following this, the KEYFAX service will be expanded to include 25 homes of paralyzed veterans, as well as other locations in VA Hines Hospital.

Hines reports continue, next page.

A Simple Instrument for Monitoring the Walking Pattern of Blind Pedestrians

J. Trimble, Ph. D., and R. Hollyfield, Ph. D.

The purpose of this project is to develop a gait measure sensitive to subtle changes in the walking patterns of blind people.

A prototype instrument has been designed, fabricated and tested. Preliminary results using experienced and inexperienced long-cane travelers suggests there are gait measures sensitive to the traveler's level of skill.

Future plans are to use the instrument for research and training. Research studies will utilize gait measures to isolate environmental factors used for navigation by blind pedestrians. Training studies will assess the utility of the instrument to follow the progress of students in orientation and mobility training.

Reference

Trimble JL, Hollyfield RL: Measuring performance by blind travelers. Proc. 4th Ann Conf Rehab Engineering, August 30–September 3, 1981.

SYSTEMS EVALUATION AND RESEARCH DESIGN CORE LABORATORY

A Study of the Effectiveness of a Blind Rehabilitation Program

Ross W. Lambert, Jr., M.D., Selwyn Becker, Ph. D., Ben Wright, Ph. D.

The purpose of this study is to assess the degree of effectiveness of the Blind Rehabilitation Center in bringing about positive changes in the lives of blind patients by developing means of predicting individual success in the rehabilitation training. In order to measure the degree to which the Blind Rehabilitation Center effects changes in patient's life states, the dimensions of life state have been defined during the course of pilot studies preparatory to the current studies. These scales, derived from the pilot studies, are used to assess each patient's life state prior to rehabilitation and again after treatment. This permits us to measure the amount of change in patients' lives which is due to rehabilitation treatment. This process will demonstrate both strengths and weaknesses in the existing program and thus lead the way to improving that program. We are creating measuring instruments or scales which can be used to evaluate any blind rehabilitation program and thus improve the quality of treatment and the efficiency of service allocation in all such programs. We use a method of test design which permits a degree of validity, reliability and generalized ability and which allows great precision in specifying the amount of a given skill or characteristic possessed by the individual patient.

Over the last year we have developed a number of instruments to assess life state. One is a general model for the rehabilitation process in the Blind Rehabilitation Center. (Courington, Lambert, Becker and Wright, 1981, and Lambert et al., 1982). Another is an inventory of attitude toward blindness which measures the attitude of the patient toward the disability and of the significant other toward the disability (Lambert, Becker, Wright, 1982, and Courington, Lambert, Becker, Wright, 1982). We have developed a mood scale which measures the level of anxiety, depression or other psychological impairment to learning (Lambert, Becker, Courington, Wright, in press). An activity and mobility inventory, which assesses the level of skill and the travel that the patient experiences, has been developed and validated on a group of patients as well. Each of these measuring instruments has been validated on a sample of at least 100 patients.

New patients are being interviewed before they reach the Blind Rehabilitation Center to assess their life state along the lines of our measuring instruments. When they return home from the Blind Rehabilitation Center, they will be measured and a change score derived to note the effect that the blind rehabilitation program has had on their life state.

We plan to continue interviewing and verifying the quality of the information with the Blind Rehabilitation Center personnel. In addition, a large number of rating scale analysis programs have been developed for use on our computer (Wright and Masters, 1982).

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*Copies of prepublication works may be obtained from R.W. Lambert, Jr., M.D.